



USER: GRAY, ILKA K (ixg)

FOLDER: K994374 - 104 pages (FOI:08007474)

COMPANY: I-FLOW CORP. (IFLOW)

PRODUCT: PUMP, INFUSION (FRN)

SUMMARY: Product: SOAKER CATHETER

DATE REQUESTED: Fri Nov 05 24:00:00 2010

DATE PRINTED: Tue Nov 23 16:56:55 2010

Note: Releasable Version

Table of Contents

510KSUM - 6 pages	1
CORRESPONDENCE - 2 pages	7
FOLDER - ANESTHESIA CONDUCTION CATHETER - 94 pages	9

MAR - 3 2000

K 994374

Summary of Safety and Effectiveness

Trade Name: ***Soaker Catheter***

Common Name: Anesthetic Catheter

Classification Name: Anesthesia Conduction Catheter

Classification Panel: Anesthesiology

All questions and/or comments concerning this document should be made to:

Stanley E. Fry

Vice President of Regulatory and Quality

I-Flow Corporation
20202 Windrow Drive
Lake Forest, CA 92630

Telephone: 949.206.2700

Fax: 949.206.2600

1.0 GENERAL INFORMATION

1.1 Statement of Equivalence

- 1.1.1 The ***Soaker Catheter*** is substantially equivalent to the (1) I-Flow IntraOp Catheter (K991543), (2) Teleflex Medical (TFX) Epidural Catheter (K840202, originally submitted by Aries), (3) B. Braun Perifix Set (K813186) and (4) the Epimed International FETH-R_KATH catheter (K981329).
- 1.1.2 The ***Soaker Catheter*** package may include components that are legally marketed (either pre-amendment devices or devices that have been granted permission to market via premarket notification regulation) such as an introducer needle or dressing.

2.0 PHYSICAL SPECIFICATIONS AND DESCRIPTIONS

2.1 Description of the *Soaker Catheter*

- 2.1.1 The ***Soaker Catheter*** is identical to the predicate IntraOp Catheter (K991543). This premarket notification adds an additional model to the *Soaker Catheter* family of catheters.
- 2.1.2 The ***Soaker Catheter*** consists of a Teleflex Medical (TFX) Epidural Catheter (K840202, originally submitted by Aries Medical) with the insertion of a hollow fiber membrane in the inner diameter of the distal end of the catheter.
 - 2.1.2.1 The catheter has a closed end tip with multiple holes arranged radially along the lateral surface at the distal end of the device.

2.2 Product Configuration

2.2.1 The following **Soaker Catheter** models will be available:

- 2.2.1.1 S0605: 20 GA with 6.5 cm (2.5 in.) infusion segment (K991543).
- 2.2.1.2 S1205: 20 GA with 12.5 cm (5.0 in.) infusion segment.
- 2.2.1.3 Each of the catheter sizes will be available as a separate catheter with a currently marketed catheter connector (a Touhy Borst type is an example of any acceptable connector) or an attached luer lock connector. The connectors will meet the ANSI specifications conical connectors.

2.2.2 The **Soaker Catheter** may consist of a kit that includes components that are legally marketed (either pre-amendment devices or devices that have been granted permission to market via premarket notification regulation).

2.2.2.1 Examples of the kit components include the following:

- 2.2.2.1.1 Teleflex Medical (TFX) "T" peel catheter over needle 18 GA X 2 ½" - 3 ½" or
- 2.2.2.1.2 Johnson & Johnson Bioclusive dressing.

2.2.3 The **Soaker Catheter** may be used in I-Flow's Pain Management Systems such as K982946 and K984502.

3.0 BIOLOGICAL SPECIFICATIONS

- 3.1 All materials in the catheter are identical in formulation to materials currently being used in other products with the same or similar uses and have a long history of use in those devices.
- 3.2 Biological testing is in conformance with ISO 10993 Part 1 for fluid path components.

4.0 CHEMICAL AND DRUG SPECIFICATIONS

- 4.1 Drug Compatibility and Stability
 - 4.1.1 There are no specific drugs referenced in the labeling for the **Soaker Catheter**.
 - 4.1.2 There are no drugs included in the **Soaker Catheter**.

5.0 INTENDED USE

- 5.1 The **Soaker Catheter** is intended to be used as follows:
 - 5.1.1 With I-Flow Corporation's PainBuster, ON-Q and Nerve Block pain management kits; and
 - 5.1.2 As a stand alone device to provide continuous or intermittent delivery of local anesthetics or narcotics to surgical wound sites and/or close proximity to nerves outside of the epidural space. Routes of administration may be intraoperative or percutaneous.
- 5.2 The catheter is single patient use only.

6.0 LABELS AND LABELING

- 6.1 I-Flow Corporation believes the proposed labels and labeling, where appropriate, meets the requirements of 21 CFR Part 801 as it relates to a determination of intended use and adequate directions for use.

7.0 STANDARDS

- 7.1 There are currently no standards established for anesthetic catheters.

8.0 PACKAGING

- 8.1 The catheter is packaged in either a Tyvek pouch or a form/fill/seal tray.

9.0 COMPARISON TO LEGALLY MARKETED DEVICES

- 9.1 The ***Soaker Catheter*** is substantially equivalent to the (1) I-Flow IntraOp Catheter submitted in K991543, (2) Teleflex Medical (TFX) Epidural Catheter (K840202, originally submitted by Aries) (3) the B. Braun Perifix Set (K813186) and (4) the Epimed International FETH-R_KATH catheter.

9.2 Device Descriptions

9.2.1 Comparisons

- 9.2.1.1 This submission is intended to notify the Federal Food and Drug Administration that I-Flow Corporation intends to add an additional model to the family of ***Soaker Catheters*** formerly referred to as the IntraOp Catheter (K991543). The new model is virtually identical to the predicate 2.5 inch Soaker Catheter except that the new model will have a 5.0 inch infusion segment.

- 9.2.1.2 All the catheters provide a catheter connector device similar to a Touhy Borst connector or a molded luer lock connector.

- 9.2.2 Based upon the data presented in this section, I-Flow Corporation has determined that the ***Soaker Catheter*** is substantially equivalent to the named predicate devices.



MAR - 3 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Stanley E. Fry
Vice President of Regulatory and Quality
I-Flow Coproration
20202 Windrow Drive
Lake Forest, California 92630

Re: K994374
Trade Name: Soaker Catheter
Regulatory Class: II
Product Code: FRN
Dated: October 23, 1999
Received: December 27, 1999

Dear Mr. Fry:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of

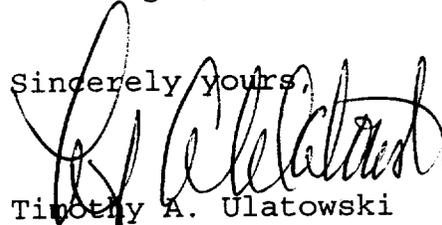
Page 2 -Mr. Fry

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4690. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K994374

Device Name: Soaker Catheter

Indications for Use:

The *Soaker Catheter* is intended to be used as follows:

1. With I-Flow Corporation's PainBuster, ON-Q and Nerve Block pain management kits; and
2. As a stand alone device to provide continuous or intermittent delivery of local anesthetics or narcotics to surgical wound sites and/or close proximity to nerves outside of the epidural space. Routes of administration may be intraoperative or percutaneous.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUED ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE) _____

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

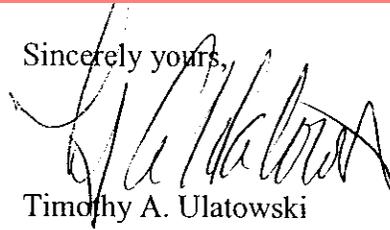
Patricia Cucchi
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K994374

(Optional Format 1-2-96)

(b)(4)

(b)(4)

Sincerely yours,



Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health

2



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAR - 3 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Stanley E. Fry
Vice President of Regulatory and Quality
I-Flow Coproration
20202 Windrow Drive
Lake Forest, California 92630

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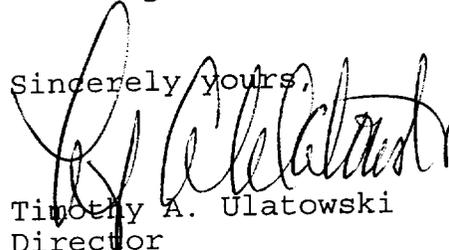
Page 2 -Mr. Fry

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Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

~

510(k) Number (if known): K994374

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUED ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

Rafaela Cucchiato
 (Division Sign-Off)
 Division of Dental, Infection Control,
 and General Hospital Devices
 510(k) Number K994374

}

Memorandum

From: Reviewer(s) - Name(s) William M. Burdick

Subject: 510(k) Number K994374

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.

De Novo Classification Candidate? YES NO

- Other (e.g., exempt by regulation, not a device, duplicate, etc.) YES NO
- Is this device subject to Postmarket Surveillance? YES NO
- Is this device subject to the Tracking Regulation? YES NO
- Was clinical data necessary to support the review of this 510(k)? YES NO
- Is this a prescription device? YES NO
- Was this 510(k) reviewed by a Third Party? YES NO
- Special 510(k)? YES NO
- Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers YES NO

This 510(k) contains:

- Truthful and Accurate Statement Requested Enclosed
(required for originals received 3-14-95 and after)
- A 510(k) summary OR A 510(k) statement
- The required certification and summary for class III devices N/A
- The indication for use form (required for originals received 1-1-96 and after)
- Material of Biological Origin YES NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

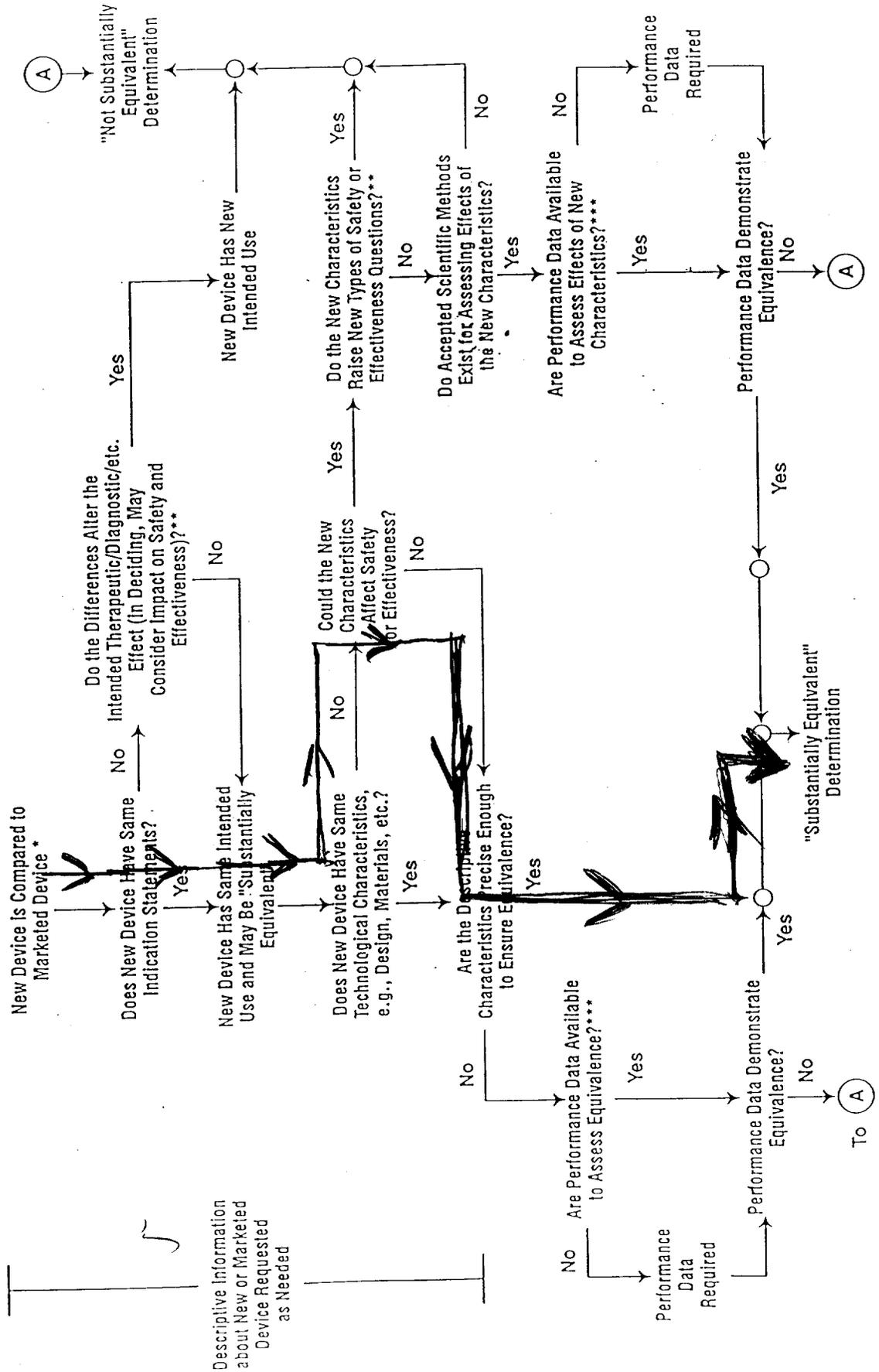
- No Confidentiality
- Confidentiality for 90 days
- Continued Confidentiality exceeding 90 days

Predicate Product Code with class: _____ Additional Product Code(s) with panel (optional): _____

80 FRN; Class III
880.5725 - Ombusjon Pump (accessory)
 Review: [Signature] (Branch Chief) [Signature] (Branch Code) 3/2/00 (Date)
 Final Review: [Signature] (Division Director) 3/3/00 (Date)

u

510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



* 510(k) Submitter must provide additional information if the relationship between marketed and "predicate" (Pre-Amendment) devices is unclear.

** This Declaration is Limited to the Data Available. Data May Vary from the Information Provided in the Pre-Amendment.

*** Performance Data Required to Assess Equivalence. Performance Data May Vary from the Information Provided in the Pre-Amendment.

Normally Based on Descriptive Information Alone, But Information is Sometimes Required.

Information is Sometimes Required. Information is Sometimes Required.

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K994374

Reviewer: William M. Burdick
 Division/Branch: DDIGD/GHDB

Device Name: Soaker Catheter

Product To Which Compared (510(K) Number If Known): Please refer to 3L of attached "510(k) REVIEW".

	YES	NO	
1. Is Product A Device	X		If NO = Stop
2. Is Device Subject To 510(k)?	X		If NO = Stop
3. Same Indication Statement?	X		If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?		X	If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?		X	If YES = Go To 8
7. Descriptive Characteristics Precise Enough?	X		If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?			If NO = Request Data
11. Data Demonstrate Equivalence?			Final Decision: SE

(Continued on Next Page.)

6

1. *Intended Use*: Please refer to #2 of attached "510(k) REVIEW".

2. *Device Description*: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device for home use or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

Please refer to #1 of attached "510(k) REVIEW".

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. *Explain why not a device*: N/A

2. *Explain why not subject to 510(k)*: N/A

3. *How does the new indication differ from the predicate device's indication*: N/A

4. *Explain why there is or is not a new effect or safety or effectiveness issue*: N/A

5. *Describe the new technological characteristics*: The "infusion length" segment of the subject device was increased, and the material comprising the hollow tubular membrane was changed from (b) (4) (b)(4)

(b) (4) (b)(4)

6. *Explain how new characteristics could or could not affect safety or effectiveness*: The catheter was tested with the modifications to infusion length and membrane material, and no change to safety and effectiveness was reported.

7. *Explain how descriptive characteristics are not precise enough*: N/A

8. *Explain new types of safety or effectiveness questions raised or why the questions are not new*: N/A

9. *Explain why existing scientific methods can not be used*: N/A

10. *Explain what performance data is needed*: N/A

11. *Explain how the performance data demonstrates that the device is or is not substantially equivalent*: N/A

ATTACH ADDITIONAL SUPPORTING INFORMATION

Please refer to the attached "510(k) REVIEW".

7

510 (K) REVIEW
K994374

DATE: February 28, 2000
FROM: William M. Burdick

COMPANY NAME: I-Flow Corporation
DEVICE NAME: Soaker Catheter

NARRATIVE DEVICE DESCRIPTION

1. Life-supporting or life sustaining: No
2. Implant (short-term or long-term): Yes (short-term)
3. Software-driven: No
4. Devices to which equivalence is claimed and manufacturer:

Catheter: Intra Op Catheter (K991543) by I-Flow Corporation.
Hollow Membrane Material: (b)(4) (b)(4)

5. Submission provides comparative specifications: Yes
comparative in vitro data: Yes
summary of animal testing: No
summary of clinical testing: No

6. Description of device and similarities and differences between device and pre-enactment/predicate devices, including indication for use, new technologies and new kinds of safety issues:

This 510(k) represented a kit with principal component being a single-use, nonpyrogenic, sterile (b)(4) (b)(4), (b)(4) analgesia/anesthesia catheter. I-Flow has assured that the kit components, probably an introducer needle and dressing, will be legally marketed medical devices. I-flow also stated that the subject device was identical to their legally marketed Intra Op Catheter (K991543) except for: 1) the extension of the infusion length to 12.5 cm. (@5 inches) instead of 6.5 cm. (@2.5 inches) for the Intra Op Catheter (please refer to telephone memo dated 2/28/00); and 2) the fabrication of the hollow tube membrane using (b)(4) (b)(4) (please refer to fax dated 2/28/00).

The catheter consisted of a Teleflex Medical (TFX) Epidural Catheter (K840202: originally submitted by Aries Medical) which had a hollow fiber membrane inserted into the inner lumen of the catheter. The tip of the catheter was closed, and multiple holes were arranged radially along the lateral surface at the distal end of the device. The membrane was intended to promote the even distribution of infusate flow through the entire array of exit holes instead of just the first few holes. This catheter model, S1205, was 20 gauge in size with an infusion length (catheter section at end of catheter with infusion holes) of 12.5 cm. (@ 5 inches).

Bench and performance testing provided satisfactory results.

The device was sterilized by (b)(4) to a SAL of 10^{-6} . Validation of the sterilization cycle was according to ANSI/AAMI/ISO (b)(4) (b)(4) I-Flow assured that residues of (b)(4) (b)(4) will not exceed FDA-proposed limits of 25, 25, and 250 parts per million.

The individual catheter will be packaged in a Tyvek pouch. The catheter with kit components will be packaged in a Tyvek form/fill/seal tray.

8

L. RECOMMENDATION:

I believe that this device is equivalent to: 80 FRN

Classification should be based on:

20 CFR 880.5725 - Infusion Pump (accessory)

Class: II



William M. Burdick
Biomedical Engineer
Division of Dental, Infection Control
And General Hospital Devices

Cc: K994374
BURDICK/Chron



I-FLOW CORPORATION

20202 Windrow Drive
Lake Forest, CA 92630
Phone (949) 206-2700
(800) 448-3569
Fax (949) 206-2600

The documents accompanying this facsimile transmission contains information which may be legally privileged and confidential. The information is intended only for the use of the recipient named below. If you have received this facsimile in error, please immediately notify us by telephone to arrange for return of the original documents to us. Any disclosure, copying, distribution or taking of any action in reliance on the contents of this faxed information is strictly prohibited.

Fax

To: Mr. Bill Burdick **From:** Stan Fry

Company: CDRH, Office of Device Evaluation **Pages:** 22

Fax: 301.594.2358 **Date:** 02/28/00

Phone: **CC:**

Subject: Re: K994374

Urgent For Review Please Comment Please Reply Please Recycle

◆ **Comments:**

Dear Mr. Burdick,

Attached are the following documents as you requested:

- 1) Revised Indications for Use page and Summary of Safety and Effectiveness with the intra-muscular and subcutaneous routes of administration deleted.
- 2) 510(k) Summary (K993860) for the Single and Dual-lumen Implantable Ports – Plastic device that utilizes polysulfone as the implantable port material.
- 3) 510(k) Summary (K990643) for the PS 15 Polysulfone Hollow Fiber Membrane Hemodialyzer device that utilizes polysulfone as the membrane material.
- 4) 510(k) Summary (K970700) for the Fresenius Polysulfone Hemodialyzer device that utilizes polysulfone as the membrane material.

Hopefully this will satisfy your inquiries and expedite release of the substantial equivalence letter.

Regards,

Stanley E. Fry
Vice President of Regulatory/Quality

10

510(k) Number (if known): K994374

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Concurrence of CDRH, Office of Device Evaluation (ODE) _____

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

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Summary of Safety and Effectiveness

Trade Name: ***Soaker Catheter***

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Classification Panel: Anesthesiology

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 - 2.1.2.1 The catheter has a closed end tip with multiple holes arranged radially along the lateral surface at the distal end of the device.

12

2.2 Product Configuration

2.2.1 The following **Soaker Catheter** models will be available:

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2.2.1.2 S1205: 20 GA with 12.5 cm (5.0 in.) infusion segment.

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3.2 Biological testing is in conformance with ISO 10993 Part 1 for fluid path components.

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4.1 Drug Compatibility and Stability

4.1.1 There are no specific drugs referenced in the labeling for the **Soaker Catheter**.

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6.0 LABELS AND LABELING

- 6.1 I-Flow Corporation believes the proposed labels and labeling, where appropriate, meets the requirements of 21 CFR Part 801 as it relates to a determination of intended use and adequate directions for use.

7.0 STANDARDS

- 7.1 There are currently no standards established for anesthetic catheters.

8.0 PACKAGING

- 8.1 The catheter is packaged in either a Tyvek pouch or a form/fill/seal tray.

9.0 COMPARISON TO LEGALLY MARKETED DEVICES

- 9.1 The **Soaker Catheter** is substantially equivalent to the (1) I-Flow IntraOp Catheter submitted in K991543, (2) Teleflex Medical (TFX) Epidural Catheter (K840202, originally submitted by Aries) (3) the B. Braun Perifix Set (K813186) and (4) the Epimed International FETH-R_KATH catheter.

9.2 Device Descriptions

9.2.1 Comparisons

- 9.2.1.1 This submission is intended to notify the Federal Food and Drug Administration that I-Flow Corporation intends to add an additional model to the family of **Soaker Catheters** formerly referred to as the IntraOp Catheter (K991543). The new model is virtually identical to the predicate 2.5 inch Soaker Catheter except that the new model will have a 5.0 inch infusion segment.

- 9.2.1.2 All the catheters provide a catheter connector device similar to a Touhy Borst connector or a molded luer lock connector.

- 9.2.2 Based upon the data presented in this section, I-Flow Corporation has determined that the **Soaker Catheter** is substantially equivalent to the named predicate devices.

K 993860

DEC - 3 1999

Catheter Innovations, Inc.
Single and Dual-Lumen Implantable Ports - Plastic

SUMMARY
Prepared November 8, 1999

1. **Submitted By:**

Catheter Innovations, Inc.
3598 West 1820 South
Salt Lake City, UT 84104-4959
Tel: (801) 954-8444
Fax: (801) 954-8484

2. **Contact Person:**

Roger L. Richins
V. P. Technology and Regulatory Affairs

3. **Device Establishment Registration No.:** 1723743
Owner/Operator No.: 9025151

4. **Device Identification:**

Trade Name: Implantable Port - Plastic
Common Name: Intravascular Implanted Port
Classification Name: Port & Catheter, Implanted, Subcutaneous, Intravascular
Classification: Unclassified
FDA Classification Advisory Committee: 80 - General Hospital
Product Code: LJT - The specific guidelines for Premarket Notification in the LJT product classification are detailed in the "Guidance on 510(k) Submissions for Implanted Infusion Ports" by the CDRH, ODE, Division of Gastroenterology/Urology and General Use Devices (October 1990)

5. **Predicate Device(s):** K 991897 - Catheter Innovations, Inc. Single and Dual-Lumen Implantable Ports (Approved to Market - October 21, 1999)

K880571 - Originally submitted as Catheter Technologies Port Implantable Vascular Access System (Approved to Market - March 4, 1988) - Currently marketed by Bard Access Systems as "BardPort™ Implanted Ports with Groshong® catheters"

K873213 - Hickman® Subcutaneous Port currently marketed by Bard Access Systems

6. **Description of Device Modification:**

Traditionally, implantable port bodies have been constructed using the same basic biocompatible materials. Port bodies are commonly manufactured from either titanium metal or polysulfone plastic. ***THIS SPECIAL 510(K) DEVICE MODIFICATION IS SUBMITTED TO GAIN APPROVAL FOR THE ADDITION OF A POLYSULFONE BODIED PORT TO OUR EXISTING PORT PRODUCT LINE. There is no difference whatsoever between this product and the predicate K991897 product, other than the use of polysulfone plastic material in the port body!*** There are no changes in design, intended use, and instructions for use or performance when compared to the approved device.

15



Catheter Innovations, Inc.
Single and Dual-Lumen Implantable Ports - Plastic

SUMMARY (Continued)

7. Device Description:

Catheter Innovations, Inc. Implantable Ports are constructed using a combination of traditional implanted port/catheter technology and materials which are well known and proven in the art (over fifteen years of successful use), Bard Access Systems BardPort™ Implanted Ports with Groshong® catheters-hereafter referred to as BardPorts™ (over eleven years in use) and our own previously approved 510(k) technology. The Catheter Innovations ports, like the BardPorts™ and other traditional ports are implanted within the body. They are used for access to the circulatory system for repeatable or periodic infusion of fluids and/or aspiration of blood. Like many currently marketed ports the Catheter Innovations ports have smooth, contoured titanium (or proposed polysulfone plastic) port bodies with either one (single-lumen) or two (dual-lumen) independent reservoirs.

A radiopaque silicone catheter with one or two lumens is provided with each port body. The catheter may come attached to the port body by the manufacturer or unattached depending on user preference. If the catheter comes attached to the port, at the time of use the health practitioner measures and cuts off the distal end of the catheter to the desired length. If the catheter is not attached to the port when it is purchased, the catheter is placed, then cut off at the proximal end to the desired length and attached to the port by the practitioner. The port is then placed in a small pocket made just under the skin. The port bodies are designed to facilitate secure seating and anchoring in the port pocket.

The ports are accessed by inserting a non-coring needle through the skin and into the self-sealing silicone septum which caps the port body reservoirs.

Both BardPorts™ and Catheter Innovations ports contain a thin silicone membrane within their construction. In both cases these membranes have a small slit or cut through them that acts as a valve. In the BardPorts™ this valve is located at the distal end of the attached catheter. In the Catheter Innovations ports the valve is located in a small plastic polysulfone housing which comes attached to the port body. The catheter is connected to this port through this housing. In both examples the valve is used to control the flow of fluids both into and out of the blood stream. The valve remains closed when the ports are not in use and when subjected to normal central venous pressures. When positive fluid pressure is applied through the reservoir, the valve opens, allowing infusion through the catheter. When negative pressure (aspiration) is applied, the valve opens, allowing for withdrawal of blood into a syringe.

8. Statement of Indications for Use:

The Catheter Innovations ports are designed for patients who require long-term access to the central venous system for administration of fluids including but not limited to hydration fluids, antibiotics, chemotherapy, analgesics, nutritional therapy, and blood products. They are also indicated for blood specimen withdrawal.

The Catheter Innovations ports, the BardPorts™ (both with and without valve), and the numerous other approved intravascular port and catheter combinations have the same indications for use: long-term access to the central venous system for administration of fluids and for blood specimen withdrawal.

SPECIAL 510(k): DEVICE MODIFICATION
Catheter Innovations, Inc.
Single and Dual-Lumen Implantable Ports - Plastic

SUMMARY (Continued)

9. Summary of Technological Characteristics of Device in Relation to Predicate Device(s):

Catheter Innovations currently markets ports which use titanium metal for their port bodies. This proposed device modification would add to our product line a group of ports that use polysulfone plastic as their body material. Both materials have been used for many years in this application by numerous medical device manufacturers, and are commonly used to help improve patient care.

Physical characteristics of Catheter Innovations ports using both titanium and polysulfone port bodies, compared to BardPorts™ with Groshong® and Hickman® catheters, demonstrate that the physical characteristics of the Catheter Innovations ports are identical to the predicate devices for all items listed in the "FDA Guidance on 510(k) Submissions for Implanted Infusion Ports". (October 1990)

Physically, the Catheter Innovations ports differ from the BardPorts™ with Groshong® catheters, only in that the valve in the Catheter Innovations port is located in the catheter-to-port adapter housing, instead of close to the distal tip of the catheter as in the Groshong® catheter.

Additionally, in the BardPorts™ with Groshong® catheters the catheters are supplied in shorter lengths. This length difference is only apparent when the product is removed from the package. In actual use, the catheters are trimmed to length so that their distal tips are located in the distal 1/3 of the Superior Vena Cava (SVC). Thus, the difference in length of catheters, as supplied, is insignificant in relation to end-use of the product.

Both BardPorts™ with Hickman® catheters and Catheter Innovations ports are open-ended, and the distal end is trimmed by the health professional in order to obtain the desired length. Because the Groshong® catheter is close-ended and removal of a distal segment would remove the valve, these catheters are trimmed at the proximal end and subsequently fitted over their port-connecting adapter. Placement and trimming of Catheter Innovations catheters, because they are open-ended, is identical to that of BardPort™ with Hickman® catheters.

Catheter Innovations three-way valve is located in the port-to-catheter adapter housing at the proximal end of the catheter, immediately adjacent to the port body, while the Groshong® three-way valve is located in the distal tip of the catheter in the distal third of the SVC, and directly in the fluid stream path. There are no new safety or effectiveness issues posed by the difference in location of these valves within the body.

Conclusion:

Based on these physical characteristic comparisons, we consider the Catheter Innovations Implantable Ports, using a polysulfone plastic body, to be substantially equivalent to the Catheter Innovations Implantable Ports using a titanium metal body. We also consider this product substantially equivalent to BardPort™ with Groshong® and Hickman® catheters as well as other currently marketed ports in their physical characteristics.

Catheter Innovations, Inc.
Single and Dual-Lumen Implantable Ports - Plastic

SUMMARY (Continued)

10. Assessment of Performance Data:

Performance test results indicate Catheter Innovations ports, using polysulfone bodies, are substantially equivalent to predicate device port/catheter combinations for all performance characteristics itemized in the "FDA Guidance on 510(k) Submissions for Implanted Infusion Ports". (October 1990)

Catheter Innovations performance characteristics related to port and valve function were compared to the predicate Catheter Innovation's ports and BardPort™ with Groshong® catheters. Comparison of all other Catheter Innovations port catheter performance characteristics were made to the range of values found for the performance of the predicate BardPort™ with Hickman® and Groshong® catheters. These comparisons indicate that the Catheter Innovations polysulfone port body with catheters performed equivalent to, or better than, the predicate devices for all performance characteristics studied.

Conclusion:

Data indicates that the performance characteristics of the Catheter Innovations ports (using both titanium and polysulfone bodies), are equivalent or superior to the currently marketed BardPort™ Implanted Ports with Groshong® and Hickman® catheters while posing no new safety, efficacy, or performance issues.

11. MRI – Compatible:

The Catheter Innovations Implantable Ports contain no ferrous materials; therefore they are not susceptible to magnetic influence and are "MRI Compatible".

12. Risk Analysis:

A risk analysis was completed on the products covered by this "SPECIAL" 510(k) DEVICE MODIFICATION. This analysis showed that the product constructed with polysulfone plastic used as the port body has the same inherent risks of use as predicate devices and all other central venous access port/catheter products. Their use should be carefully considered before placement. Their placement and care should only be performed by persons knowledgeable of the risks involved and qualified in the procedures required.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 3 1999

Mr. Roger L. Richins
V.P. Technology and Regulatory Affairs
Catheter Innovations, Inc.
3598 West 1820 South
Salt Lake City, Utah 84104-4959

Re: K993860
Trade Name: Single and Dual-Lumen Implantable Ports -
Plastic
Regulatory Class: Unclassified
Product Code: LJY
Dated: November 8, 1999
Received: November 15, 1999

Dear Mr. Richins:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any

19

Page 2 - Mr. Richins

obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



fm

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

20

510(k) Number (if known): K993860

Device Name: Catheter Innovations Implantable Ports - Plastic

Indications For Use:

The Catheter Innovations Implantable Port is designed for patients who require long-term access to the central venous system for administration of fluids including but not limited to hydration fluids, antibiotics, chemotherapy analgesics, nutritional therapy, and blood products. It is also indicated for blood specimen withdrawal.

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Paloma Cuevas

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K993860

Prescription Use
(Per 21 CFR 801.108)

OR

Over-The-Counter

vi.1

(Optional Format 1-2-96)

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ATT04001.txt

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12/7/99

K990643

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS [As Required by 21 CFR 807.92(c)]

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92(a).

I. SUBMITTER INFORMATION

- a. Company Name: Althin Medical, Inc.
- b. Company Address: 14620 NW 60th Avenue
Miami Lakes, Florida 33014-9308
- c. Company Phone: (305) 823-5240
- d. Contact Person: Amaury Sanchez
Senior Regulatory Compliance
Coordinator
- e. Date Summary Prepared: February 24, 1999

II. DEVICE IDENTIFICATION

- a. Trade/Proprietary Name: PS 150 Hemodialyzer
- b. Common Name: Hemodialyzer
- c. Classification Name: High Permeability Hemodialyzer 21 CFR
876.5960

III. Substantially Equivalent Legally Marketed Device:

Company	Device	510(k) No.	Date Cleared
Althin Medical, Inc.	Altrex 170 Hemodialyzer	K945597	3/8/95
Fresenius Medical Care	Fresenius F60 Polysulfone Dialyzer	K852251	7/25/85

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23

The PS 15® Hemodialyzer is substantially equivalent to other predicate devices currently in commercial distribution in terms of their intended use. The fundamental technical characteristics are similar to those of the predicate devices.

IV. DEVICE DESCRIPTION

The PS 15® Hemodialyzer consists of approximately 13,000 polysulfone hollow fibers encapsulated in polyurethane resin with an outer housing and headers made of Polycarbonate. The device is packaged in a blister package composed of Glycol modified Polyethylene Terephthalate for the bottom web, and a foil laminate for the top web.

The PS 15® Hemodialyzer has two compartments, the blood compartment and the dialysate compartment, separated by the polysulfone permeable membrane. Blood flows from the patient access site through the tubing of the extracorporeal system and accessories to the blood compartment of the dialyzer. From the blood compartment, undesirable substances in the blood pass through the membrane into the dialysate compartment of the dialyzer. Circulation and monitoring of dialysate flow through the dialysate compartment is controlled by the dialysate delivery system, while the ultrafiltration controller prevents excessive loss of water from the patient's blood.

V. INTENDED USE OF THE DEVICE

The disposable PS 15® Hemodialyzer is intended for use in conjunction with commercially available blood tubing, blood access devices and related hemodialysis equipment. The intended use of the PS 15® Hemodialyzer and predicate Altrex 170 Hemodialyzer is identical in that the devices are intended for hemodialysis in patients with acute or chronic renal failure, when conservative therapy is judged to be inadequate. Both devices are labeled as sterile, non-pyrogenic, and for single use only. The devices are restricted to sale by or on the order of a physician.

VI. COMPARISON OF TECHNICAL CHARACTERISTICS

The design configuration of the PS 15® Hemodialyzer is similar to legally marketed devices from Althin Medical, Inc. and polysulfone membrane from Fresenius Medical Care.

With the exception of polysulfone, the PS 150 Hemodialyzer and predicate Altrex 170 use identical materials, similar manufacturing processes, the same package and are gamma sterilized.

The polysulfone membrane used in the PS 150 Hemodialyzer is substantially equivalent to other polysulfone membranes marketed by Fresenius Medical Care. Results from the functional, chemical and biological tests demonstrate that the PS 150 Hemodialyzer is equivalent to a legally marketed device.

A comparison of the features of the PS 150 Hemodialyzer and those of the previously cleared predicate device are presented in the following table.

Feature	PS 150 Hemodialyzer	Altrex 170 Hemodialyzer
Classification Name	High Permeability Hemodialyzer or artificial kidney	High Permeability Hemodialyzer or artificial kidney
Classification	Class III device per 21 CFR 876.5860(b)	Class III device per 21 CFR 876.5860(b)
Panel	Gastroenterology and Urology	Gastroenterology and Urology
Product Code	78KDI	78KDI
Indications for Use	Same	Same
Product Specifications	Similar	Similar
Component configuration	Same	Same
Component functions	Same	Same
Compatible Hemodialysis Equipment	Same	Same
Labeling	Similar content	Similar content
Intended use	Same	Same
Labeled sterile, non-pyrogenic for single use only	Yes	Yes
Restricted to sale by or on Order of a Physician	Yes	Yes
Materials	Polysulfone Polycarbonate Polyurethane ABS Polyethylene	Cellulose Acetate Polycarbonate Polyurethane ABS Polyethylene
Design	Similar	Similar
Hemolysis	< 3% of Control	< 3% of Control
Pyrogenicity	Non-pyrogenic	Non-pyrogenic
Acute Toxicity	Meets USP	Meets USP
Sterility	Sterile	Sterile
Leakage	No Leaks	No Leaks
Sterilization Method	Gamma	Gamma
Packaging	Foil/PETG tray	Foil/PETG tray

VII. FUNCTIONAL TESTING

Functional testing has been conducted to evaluate the performance of the PS 150 Hemodialyzer. The results of the functional testing attest that the PS 150 Hemodialyzer conforms to its specifications and has demonstrated the suitability of the PS 150 Hemodialyzer for its intended use.

	PS 150 Hemodialyzer	**Altrex 170	**Fresenius F60
Total Blood Volume Measured (ml)	79	91	83
Effective Membrane Surface Area (m ²)	1.5	1.61	1.25
Wall Thickness (μ)	20	30	40
Maximum TMP	500	500	650
Clearance (ml/min)*			
Urea	171	178	185
Creatinine	155	163	172
Phosphate	141	155	170
B ₁₂	73	106	118

*Q_b 200, Q_d 500 *in vitro* Q_r 10 ml/min UFR

***In Vitro* Q_r 0.0 ml/min

The Althin Medical, Inc., PS 150 Hemodialyzer is similar in design, construction, indication for use, and performance characteristics to other commercially available hemodialyzers. The results from nonclinical tests demonstrate that the PS 150 Hemodialyzer is substantially equivalent to predicate devices.

VIII. BIOCOMPATIBILITY TESTING

All appropriate biocompatibility tests have been performed. The following tests were performed:

Test Name	Results
Cytotoxicity Study (USP Elution Method)	Pass
ISO Sensitization Study in the Guinea Pig (Maximization Method)	Pass
Subchronic Intravenous Toxicity Study in the Rat	Pass
Acute Intracutaneous Reactivity Study in the Rabbit	Pass
Acute Systemic Toxicity Study in the Mouse	Pass
ISO Muscle Implantation Study in the Rabbit	Pass
Genotoxicity: Salmonella typhimurium Reverse Mutation Study	Pass
Genotoxicity: Sister Chromatid Exchange Study	Pass
Genotoxicity: Chromosomal Aberration Study in Mammalian Cells	Pass
Rabbit Pyrogen Study	Pass
Hemolysis Study <i>In Vitro</i> Procedure	Pass
Microtoxicity and Hemolysis Test	Pass

546

26

The results of the biocompatibility testing demonstrate that the PS 15® Hemodialyzer conforms to the specifications set forth. The subject and legally marketed devices conform to similar specifications.

IX. Conclusions

The information included in this notification demonstrate that the PS 15® Hemodialyzer and predicate device are similar in design, materials, manufacturing processes, performance, safety, effectiveness, intended uses, indications, labeling and instructions for use. Therefore, based on the information provided in this premarket notification, the PS 15® Hemodialyzer is considered substantially equivalent to the predicate devices.

27 547



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 7 1999

Mr. Amaury Sanchez, RAC
Senior Regulatory Compliance Coordinator
Althin Medical, Inc.
14620 N.W. 60th Avenue
Miami Lakes, FL 33014

Re: K990843
PS 15^o Polysulfone Hemodialyzer
Dated: June 24, 1999
Received: June 28, 1999
Regulatory Class: III
21 CFR §876.5860/Procode: 76 KDI

Dear Mr. Sanchez:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.87). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-8597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K990643

Device Name: **PS 15® Polysulfone Hollow Fiber Membrane Hemodialyzer**

Indications for Use: **The PS 15® Hemodialyzer is intended for hemodialysis in patients with acute or chronic renal failure, when conservative therapy is judged to be inadequate.**

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

OR Over-The-Counter Use

Coleen M. Pollard
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
S10(k) Number K990643

2
29

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 15 1998

Mr. Tom Folden
Director, Product Development
Fresenius Medical Care, N.A.
2637 Shadelands Drive
Walnut Creek, CA 94598

Re: K970700
Multiple Use Labeling for Hemoflow Dialyzers
Models F4, F5, F6, F7, F8, F60M, F70M, F80M,
F60A, F70A, F80A, F60B, F70B, F80B
Dated: June 18, 1998
Received: June 23, 1998
Regulatory class: II and III
21 CFR §876.5820/Product code: 78 MSE
and 21 CFR §876.5860/Product code: 78 MSF

Dear Mr. Folden:

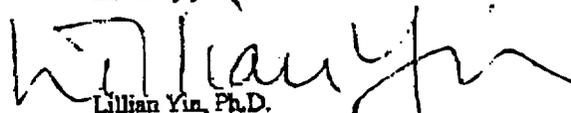
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) pre-market notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to pre-market notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

30

510 (k) Number (if Known): K970700

Device Name: Fresenius Polysulfone Hemodialyzers

Indications for Use:

Hemoflow dialyzers are designed for use in acute or chronic hemodialysis therapies as either single use or multiple use.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

_____ Concurrence of CDRH, Office of Device Evaluation (ODE) _____

Prescription Use or Over the Counter Use _____

William [Signature]
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K970700

806
31

MEMORANDUM OF TELEPHONE CONVERSATION

DATE: February 28, 2000

TO: Stanley E. Fry, VP, Regulatory and Quality
Shane Noehre, Regulatory Affairs Manager
I-Flow Corporation
20202 Window Drive
Lake Forest, CA 92630
Tel.: (949)206-2700
Fax: (949)206-2600

FROM: William M. Burdick
HHS/PHS/FDA/ODE/DDIGD/GHDB
HFZ-480
9200 Corporate Blvd.
Rockville, MD 20850
Tel.: (301)594-1287
Fax: (301)594-2358

SUBJECT: 510K Number K994374 - Soaker Catheter by I-Flow Corporation

This 510(k) represented a kit with principal component being a single-use, nonpyrogenic, sterile (b)(4) (b)(4) (b)(4) analgesia/anesthesia catheter. I-Flow assured that the kit components, probably an introducer needle and dressing, will be legally marketed medical devices. I-flow also stated that the subject device was "identical" to their legally marketed Intra Op Catheter (K991543).

The catheter consisted of a Teleflex Medical (TFX) Epidural Catheter (K840202: originally submitted by Aries Medical) which had a hollow fiber membrane inserted into the inner lumen of the catheter. The tip of the catheter was closed, and multiple holes were arranged radially along the lateral surface at the distal end of the device. The membrane was intended to promote the even distribution of infusate flow through the entire array of exit holes instead of just the first few holes. This catheter model, S1205, was 20 gauge in size with an infusion length (catheter section at end of catheter with infusion holes) of 12.5 cm. (@ 5 inches).

I called Mr. Fry in order to obtain information which I needed to continue the premarket review of this submission. He asked if his Regulatory Affairs Manager, Mr. Noehre, could join the discussion, and I agreed. A summary of the conversation follows:

1. I asked Mr. Fry if he recalled the conversation we had regarding the Indications for Use for the predicate Intra Op Catheter (K991543), which took place during my review of the submission. The conversation concerned changing the intended use for the Intra Op to exclude intramuscular and subcutaneous infusion. He replied that he did remember modifying both the Indications for Use form and the intended use as stated in the Summary of Safety and Effectiveness to reflect this change. I told him that, for some reason, the old Indications for Use form had been placed on the Web, and I explained that this would be corrected, soon. I told him that I brought this up, because his new Indications for Use and Summary of Safety and Effectiveness had the unmodified, original forms for both and needed to be modified as stated above. He agreed to do so.
2. It was mentioned in the submission that the subject catheter was "identical"

to the predicate Intra Op except for the extension of the infusion length to 12.5 cm. (@5 inches) instead of 6.5 cm. (@2.5 inches). I asked if this was so, and Mr. Fry responded in the affirmative.

3. In regards to the above, I stated that an additional material to the (b)(4) (b)(4) was stated as a component of the inner hollow (b)(4)(b)(4). This material was (b)(4)(b)(4) and both Mr. Fry and Mr. Noehre confirmed that they intended to use the (b)(4)(b)(4) instead of the predicate (b)(4) (b)(4). They explained that they preferred that particular (b)(4) (b)(4) material over the (b)(4) (b)(4) and assured that the new material was used in legally marketed medical device membranes that filtered blood. I asked for a 510(k) document control number to verify the new material, and they stated that they would fax it to me along with the revised Indications for Use form and the Summary of Safety and Effectiveness.

I concluded our conversation by informing them that I would hold their submission until I received the faxed information.

Later in the day, They sent me the additional information I had requested, and it was satisfactory.

William M. Burdick
William M. Burdick
Biomedical Engineer

cc. K994374
CHRON file

Screening Checklist

For all Premarket Notification 510(k) Submissions

Device Name: <u>Soaker Cabinet</u>						K994374						
Submitter (Company): <u>I-flow Corp</u>												
Items which should be included (circle missing & needed information)						S P E C I A L		A B B R E V I A T E D		T R A D I T I O N A L		✓ IF ITEM IS NEEDED AND IS MISSING
						YES	NO	YES	NO	YES	NO	
1. Cover Letter clearly identifies Submission as:										✓		
a) "Special 510(k): Device Modification"						GO TO # 2,3		GO TO # 2,4,5		GO TO # 2,4,5		
b) "Abbreviated 510(k)"												
c) Traditional 510(k)												
2. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS												✓ IF ITEM IS NEEDED
Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(i)						NA		YES		NO		AND IS MISSING
						SPECIALS		ABBREVIATED		TRADITIONAL		
						YES	NO	YES	NO	YES	NO	
a) trade name, classification name, establishment registration number, device class										✓		
b) OR a statement that the device is not yet classified						FDA-may be a classification request; see coordinator						
c) identification of legally marketed equivalent device						NA				✓		
d) compliance with Section 514 - performance standards						NA				✓		
e) address of manufacturer										✓		
f) Truthful and Accurate Statement										✓		
g) Indications for Use enclosure										✓		
h) SMDA Summary or Statement (FOR ALL DEVICE CLASSES)										✓		
i) Class III Certification & Summary (FOR ALL CLASS III DEVICES)										✓		
j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals										✓		
k) Proposed Labeling:										✓		
i) package labeling (user info)										✓		
ii) statement of intended use										✓		
iii) advertisements or promotional materials										✓		
i) MRI compatibility (if claimed)										✓		
l) Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include:										✓		
i) Labeling										✓		
ii) intended use										✓		
iii) physical characteristics										✓		
iv) anatomical sites of use										✓		
v) performance (bench, animal, clinical) testing						NA						
vi) safety characteristics						NA						
m) If kit, kit certification												
3. "SPECIALS" - ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II, III OR RESERVED CLASS I DEVICE												
a) Name & 510(k) number of legally marketed (unmodified) predicate device												
b) STATEMENT - INTENDED USE AND INDICATIONS FOR												
						* If no - STOP not a special						

USE OF MODIFIED DEVICE AS DESCRIBED IN ITS LABELING HAVE NOT CHANGED*				
c) STATEMENT - FUNDAMENTAL SCIENTIFIC TECHNOLOGY OF THE MODIFIED DEVICE HAS NOT CHANGED*			* If no - STOP not a special	
d) Design Control Activities Summary				
i) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis				
ii) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied				
iii) A declaration of conformity with design controls. The declaration of conformity should include:				
1) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met				
2) A statement signed by the individual responsible, that manufacturing facility is in conformance with design control procedure Requirements as specified in 21 CFR 820.30 and the records are available for review.				

	SPECIALS		ABBREVIATED		TRADITIONAL		✓ IF ITEM IS NEEDED AND IS MISSING
	YES	NO	YES	NO	YES	NO	
4. ABBREVIATED 510(K): SPECIAL CONTROLS/CONFORMANCE TO RECOGNIZED STANDARDS - PLEASE FILL OUT THE STANDARDS ABBREVIATED FORM ON THE H DRIVE							
a) For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type							
b) If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.							
c) For a submission, which relies on a recognized standard, a declaration of conformity to the standard. The declaration should include the following:							
i) An identification of the applicable recognized consensus standards that were met							
ii) A specification, for each consensus standard, that all requirements were met, except for							

2}

inapplicable requirements or deviations noted below
iii) An identification, for each consensus standard, of any way(s) in which the standard may have been adapted for application to the device under review, e.g., an identification of an alternative series of tests that were performed
iv) An identification, for each consensus standard, of any requirements that were not applicable to the device
v) A specification of any deviations from each applicable standard that were applied
vi) A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference
vii) Name/address of test laboratory/certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations
d) Data/information to address issues not covered by guidance documents, special controls, and/or recognized standards

5. Additional Considerations: (may be covered by Design Controls)									
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:									✓
i) component & material									✓
ii) identify patient-contacting materials									✓
iii) biocompatibility of final sterilized product									✓
b) Sterilization and expiration dating information:									✓
i) sterilization method									✓
ii) SAL									✓
iii) packaging									✓
iv) specify pyrogen free									✓
v) ETO residues									✓
vi) radiation dose									✓
c) Software validation & verification:									
i) hazard analysis									
ii) level of concern									
iii) development documentation									
iv) certification									

Items shaded under "NO" are necessary for that type of submission. Circled items and items with checks in the "Needed & Missing" column must be submitted before acceptance of the document. >

Passed Screening Yes No
 Date:

Reviewer: William M. Burdick
 Concurrence by Review Branch: 2/15/00

[Handwritten signature]

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K _____

Reviewer: _____

Division/Branch: _____

Device Name: _____

Product To Which Compared (510(K) Number If Known): _____

	YES	NO	
1. Is Product A Device			If NO = Stop
2. Is Device Subject To 510(k)?			If NO = Stop
3. Same Indication Statement?			If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?			If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?			If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?			If NO = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

37

1. Intended Use:

2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device for home use or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication:
4. Explain why there is or is not a new effect or safety or effectiveness issue:
5. Describe the new technological characteristics:
6. Explain how new characteristics could or could not affect safety or effectiveness:
7. Explain how descriptive characteristics are not precise enough:
8. Explain new types of safety or effectiveness questions raised or why the questions are not new:
9. Explain why existing scientific methods can not be used:
10. Explain what performance data is needed:
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

38

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		✓
2. Did we grant expedited review?		✓
3. Have you verified that the Document is labeled Class III for GMP purposes?		✓
4. If, not, has POS been notified?	✓	
5. Is the product a device?		✓
6. Is the device exempt from 510(k) by regulation or policy?	✓	
7. Is the device subject to review by CDRH?		
8. Are you aware that this device has been the subject of a previous NSE decision?		✓
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		✓
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		✓

39

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

December 28, 1999

I-FLOW CORP.
20202 WINDROW DR.
LAKE FOREST, CA 92630
ATTN: STANLEY E. FRY

510(k) Number: K994374
Received: 27-DEC-1999
Product: SOAKER CATHETER

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance (DSMA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsmamain.html> or me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff
Office of Device Evaluation
Center for Devices and Radiological Health

UP

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
Premarket Submission Cover Sheet

Date of Submission: 10/23/1999

FDA Document Number: K 994374

Section A: Type of Submission

- | | | | |
|---------------------------------------------------|-----------------------------------------|----------------------------------------|-------------------------------------------------------|
| <input checked="" type="checkbox"/> 510(k) | <input type="checkbox"/> IDE | <input type="checkbox"/> PMA | <input type="checkbox"/> PMA Supplement - Regular |
| <input type="checkbox"/> 510(k) Add'l information | <input type="checkbox"/> IDE Amendment | <input type="checkbox"/> PMA Amendment | <input type="checkbox"/> PMA Supplement - Special |
| | <input type="checkbox"/> IDE Supplement | <input type="checkbox"/> PMA Report | <input type="checkbox"/> PMA Supplement - 30 day |
| | <input type="checkbox"/> IDE Report | | <input type="checkbox"/> PMA Supplement - Panel Track |

Section B1: Reason for Submission — 510(k)s Only

- New device
- Additional or expanded indications
- Change in technology, design, materials, or manufacturing process
- Other reason (specify):

Section B2: Reason for Submission — PMAs Only

- | | | |
|-------------------------------------------------------------|-------------------------------------------------------------------------|----------------------------------------------|
| <input type="checkbox"/> New device | <input type="checkbox"/> Change in design, component, or specification: | <input type="checkbox"/> Location change: |
| <input type="checkbox"/> Withdrawal | <input type="checkbox"/> Software | <input type="checkbox"/> Manufacturer |
| <input type="checkbox"/> Additional or expanded indications | <input type="checkbox"/> Color Additive | <input type="checkbox"/> Sterilizer |
| <input type="checkbox"/> Licensing agreement | <input type="checkbox"/> Other (specify below) | <input type="checkbox"/> Packager |
| <input type="checkbox"/> Labeling change: | <input type="checkbox"/> Process change: | <input type="checkbox"/> Report submission: |
| <input type="checkbox"/> Indications | <input type="checkbox"/> Manufacturer | <input type="checkbox"/> Annual or periodic |
| <input type="checkbox"/> Instructions | <input type="checkbox"/> Sterilizer | <input type="checkbox"/> Post-approval study |
| <input type="checkbox"/> Performance Characteristics | <input type="checkbox"/> Packager | <input type="checkbox"/> Adverse reaction |
| <input type="checkbox"/> Shelf life | | <input type="checkbox"/> Device defect |
| <input type="checkbox"/> Trade name | <input type="checkbox"/> Response to FDA correspondence (specify below) | <input type="checkbox"/> Amendment |
| <input type="checkbox"/> Other (specify below) | <input type="checkbox"/> Request for applicant hold | |
| <input type="checkbox"/> Change in ownership | <input type="checkbox"/> Request for removal of applicant hold | |
| <input type="checkbox"/> Change in correspondent | <input type="checkbox"/> Request for extension | |
| <input type="checkbox"/> Other reason (specify): | <input type="checkbox"/> Request to remove or add manufacturing site | |

RECEIVED
 2 / DEC 99
 FDA/CDRH
 ODE/MC

Section B3: Reason for Submission — IDEs Only

- | | | |
|---------------------------------------------------------|----------------------------------------------------|----------------------------------------------------------------------|
| <input type="checkbox"/> New device | <input type="checkbox"/> Change in: | <input type="checkbox"/> Response to FDA letter concerning: |
| <input type="checkbox"/> Addition of institution | <input type="checkbox"/> Correspondent | <input type="checkbox"/> Conditional approval |
| <input type="checkbox"/> Expansion / extension of study | <input type="checkbox"/> Design | <input type="checkbox"/> Deemed approved |
| <input type="checkbox"/> IRB certification | <input type="checkbox"/> Informed consent | <input type="checkbox"/> Deficient final report |
| <input type="checkbox"/> Request hearing | <input type="checkbox"/> Manufacturer | <input type="checkbox"/> Deficient progress report |
| <input type="checkbox"/> Request waiver | <input type="checkbox"/> Manufacturing | <input type="checkbox"/> Deficient investigator report |
| <input type="checkbox"/> Termination of study | <input type="checkbox"/> Protocol - feasibility | <input type="checkbox"/> Disapproval |
| <input type="checkbox"/> Withdrawal of application | <input type="checkbox"/> Protocol- other | <input type="checkbox"/> Request extension of time to respond to FDA |
| <input type="checkbox"/> Unanticipated adverse effect | <input type="checkbox"/> Sponsor | <input type="checkbox"/> Request meeting |
| <input type="checkbox"/> Emergency use: | <input type="checkbox"/> Report submission: | <input type="checkbox"/> IOL submissions only: |
| <input type="checkbox"/> Notification of emergency use | <input type="checkbox"/> Current investigator | <input type="checkbox"/> Change in IOL style |
| <input type="checkbox"/> Additional information | <input type="checkbox"/> Annual progress | <input type="checkbox"/> Request for protocol waiver |
| <input type="checkbox"/> Other reason (specify): | <input type="checkbox"/> Site waiver limit reached | |
| | <input type="checkbox"/> Final | |

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Section C

Product Classification

Product code: 73 BSO

C.F.R. Section: 868.5120

Device class:

- Class I Class II
 Class III Unclassified

Classification panel: Anesthesiology

Section D

Information on 510(k) Submissions

Product codes of devices to which substantial equivalence is claimed:

1 73 BSO	2 73 CAZ	3	4
5	6	7	8

Summary of, or statement concerning, safety and effectiveness data:

- 510(k) summary attached
 510(k) statement

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 K840202	1 Epidural Catheter	1 TFX Medical (Aries Med)
2 K813186	2 Perifix Set	2 B Braun Medical
3 K981329	3 FETH-R-KATH	3 Epimed International
4 K991543	4 IntraOp Catheter <i>MEB-HO</i>	4 I-Flow Corporation
5	5	5
6	8	8

Section E

Product Information — Applicable to All Applications

Common or usual name or classification name: Anesthesia Conduction Catheter

Trade or proprietary or model name	Model number
1 Soaker Catheter	1
2	2
3	3
4	4
5	5
6	6

FDA document numbers of all prior related submissions (regardless of outcome):

1 K991543	2	3	4	5	6
7	8	9	10	11	12

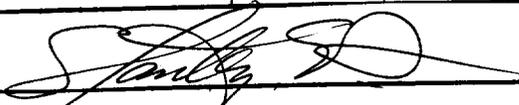
Data included in submission: Laboratory testing Animal trials Human trials

Indications (from labeling): The Soaker Catheter is intended to be used in the following two manners: 1. With I-Flow's PainBuster, ON-Q and Nerve Block pain management kits; and 2. As a stand alone device to provide continuous or intermittent delivery of local anesthetics or narcotics to surgical wound sites and/or close proximity to nerves outside of the epidural space. Routes of administration include intraoperative, intramuscular, subcutaneous or percutaneous.

4V

			FDA Document Number:		
Section F Manufacturing / Packaging / Sterilization Sites					
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA establishment registration number: 2026095		<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract manufacturer	
<input type="checkbox"/> Contract sterilizer <input type="checkbox"/> Repackager / relabeler					
Company / Institution name: I-Flow Corporation					
Division name (if applicable):				Phone number (include area code): (949) 206-2700 ext. 2670	
Street address: 20202 Windrow Drive				FAX number (include area code): (949) 206-2603	
City: Lake Forest		State / Province: CA		Country: U.S.A.	
ZIP / Postal Code: 92630					
Contact name: Stanley E. Fry					
Contact title: Vice President of Regulatory and Quality					
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA establishment registration number:		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract manufacturer	
<input type="checkbox"/> Contract sterilizer <input type="checkbox"/> Repackager / relabeler					
Company / Institution name:					
Division name (if applicable):				Phone number (include area code): ()	
Street address:				FAX number (include area code): ()	
City:		State / Province:		Country:	
ZIP / Postal Code:					
Contact name:					
Contact title:					
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA establishment registration number:		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract manufacturer	
<input type="checkbox"/> Contract sterilizer <input type="checkbox"/> Repackager / relabeler					
Company / Institution name:					
Division name (if applicable):				Phone number (include area code): ()	
Street address:				FAX number (include area code): ()	
City:		State / Province:		Country:	
ZIP / Postal Code:					
Contact name:					
Contact title:					

43

				FDA Document Number:
Section G Applicant or Sponsor				
Company / Institution name: I-Flow Corporation			FDA establishment registration number: 2026095	
Division name (if applicable):			Phone number (include area code): (949) 206-2700 ext. 2670	
Street address: 20202 Windrow Drive			FAX number (include area code): (949) 206-2603	
City: Lake Forest	State / Province: CA	Country: U.S.A.	ZIP / Postal Code: 92630	
Signature: 				
Name: Stanley E. Fry				
Title: Vice President of Regulatory and Quality				
Section H Submission correspondent (if different from above)				
Company / Institution name:				
Division name (if applicable):			Phone number (include area code): ()	
Street address:			FAX number (include area code): ()	
City:	State / Province:	Country:	ZIP / Postal Code:	
Contact name:				
Contact title:				

Your voluntary completion of this Premarket Submission Cover Sheet will not affect any FDA decision concerning your submission, but will help FDA's Center for Devices and Radiological Health process your submission more efficiently. The information you provide should apply *only* to a single accompanying submission. Please do not send cover sheets for any previous submissions. See the instructions for additional information on completing the cover sheet. If you have a question concerning completion of the cover sheet, please contact the Division of Small Manufacturers Assistance at (800) 638-2041 or (301) 443-6597.

44

Premarket Notification - 510(k)

Via Federal Express
December 23, 1999

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center HFZ - 401
9200 Corporate Blvd.
Rockville, Maryland 20850

Reviewing Staff:

In accordance with §510(k) of the Federal Food, Drug, and Cosmetic Act and in conformance with Title 21 CFR §807.81, I-Flow Corporation is submitting this premarket notification for the *Soaker Catheter* prior to the introduction into interstate commerce for commercial distribution. This submission is the second in a series of premarket notifications for the *Soaker Catheter* and offers a catheter with a 5 inch infusion segment compared to the 2.5 inch length in the earlier filing.

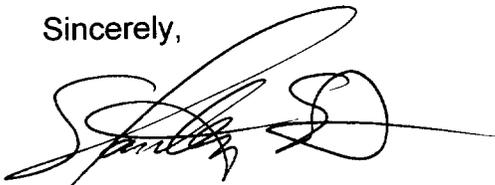
The *Soaker Catheter* is substantially equivalent to the original IntraOp Catheter (K991543) marketed by I-Flow Corporation, the B. Braun Epidural Catheter, the TFX Catheter and the Epimed International FETH-R_KATH catheter .

All questions and/or comments concerning this document should be made to:

Stanley E. Fry
Vice President Regulatory and Quality

I-Flow Corporation
20202 Windrow Drive
Lake Forest, CA 92630
Telephone: 949.206.2700
Fax: 949.206.2600

Sincerely,



Stanley E. Fry
Vice President Regulatory and Quality

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2 / Dec 99 11 35
FDA/CDRH/OCE/DMC

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**PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT
(As required by 21 CFR 807.87(j))**

I certify that, in my capacity as the Vice President of Regulatory and Legal Affairs of I-Flow Corporation, I believe to the best of my knowledge, that all data and information submitted in the premarket notification for the **Soaker Catheter** are truthful and accurate and that no material fact has been omitted.


Signature

Stanley E. Fry, Vice President of Regulatory and Quality

Name

Title

I-Flow Corporation

Company

12/23/99

Dated

K 994374

Premarket Notification - 510(k) Number

lib

510(k) Number (if known): K994374

Device Name: Soaker Catheter

Indications for Use:

The **Soaker Catheter** is intended to be used as follows:

1. With I-Flow Corporation's PainBuster, ON-Q and Nerve Block pain management kits;
and
2. As a stand alone device to provide continuous or intermittent delivery of local anesthetics or narcotics to surgical wound sites and/or close proximity to nerves outside of the epidural space. Routes of administration may be intraoperative, intramuscular, subcutaneous or percutaneous.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUED ON ANOTHER PAGE IF NEEDED)

_____ Concurrence of CDRH, Office of Device Evaluation (ODE) _____

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

47

TABLE OF CONTENTS

1.0	GENERAL INFORMATION	Page 1
2.0	PHYSICAL SPECIFICATIONS AND DESCRIPTION	Page 1
3.0	OPERATIONS SPECIFICATIONS AND DESCRIPTION	Page 3
4.0	BIOLOGICAL SPECIFICATIONS.....	Page 4
5.0	CHEMICAL AND DRUG SPECIFICATIONS	Page 5
6.0	INTENDED USE.....	Page 5
7.0	LABELS AND LABELING	Page 6
8.0	STANDARDS	Page 6
9.0	PACKAGING	Page 6
10.0	STERILIZATION INFORMATION	Page 6
11.0	COMPARISON TO LEGALLY MARKETED DEVICES	Page 7

Appendix A - Soaker Catheter Drawing

Appendix B - Soaker Catheter Labeling

Appendix C – Predicate Labeling

Appendix D – Hollow Fiber Material Sheet

Appendix E – Biological Safety Tests of Hollow Fiber

Appendix F - Summary of Safety and Effectiveness

48

1.0 GENERAL INFORMATION

1.1 Purpose of Submission

1.1.1 This submission is intended to notify the Federal Food and Drug Administration that I-Flow Corporation intends to add an additional model to the family of **Soaker Catheters** formerly referred to as the IntraOp Catheter (K991543). The new model is virtually identical to the predicate 2.5 inch Soaker Catheter except that the new model will have a 5.0 inch infusion segment.

Note: I-Flow has changed the name from IntraOp Catheter submitted in K991543 to Soaker Catheter.

1.1.2 Trade Name: **Soaker Catheter**

1.1.3 Common Name: Anesthetic Catheter

1.1.4 Classification Name: Anesthesia Conduction Catheter

1.1.5 Classification Panel: Anesthesiology

1.2 Statement of Equivalence

1.2.1 The **Soaker Catheter** is substantially equivalent to the (1) I-Flow IntraOp Catheter (K991543), (2) Teleflex Medical (TFX) Epidural Catheter (K840202, originally submitted by Aries), (3) B. Braun Perifix Set (K813186) and (4) the Epimed International FETH-R_KATH catheter (K981329).

1.2.2 The **Soaker Catheter** package may include components that are legally marketed (either pre-amendment devices or devices that have been granted permission to market via premarket notification regulation) such as an introducer needle or dressing.

2.0 PHYSICAL SPECIFICATIONS AND DESCRIPTIONS

2.1 Description of the **Soaker Catheter**

2.1.1 The **Soaker Catheter** is identical to the predicate IntraOp Catheter (K991543). This premarket notification adds an additional model to the Soaker Catheter family of catheters.

2.1.2 The **Soaker Catheter** consists of a Teleflex Medical (TFX) Epidural Catheter (K840202, originally submitted by Aries Medical) with the insertion of a hollow fiber membrane in the inner diameter of the distal end of the catheter.

2.1.2.1

(b) (4)

(b)(4)

2.1.2.2 The catheter has a closed end tip with multiple holes arranged radially along the lateral surface at the distal end of the device.

2.1.2.3 The length of the multiple holes corresponds to the infusion segment which equals the length of the hollow fiber membrane.

2.1.2.4 The addition of the hollow fiber membrane to the inner lumen of the catheter allows drug delivery to be distributed across the full

6
11

length of holes rather than just the first few holes. (See demonstration picture in Appendix A.)

2.1.2.5 The distal end of the catheter will be placed in the wound site prior to final closure or along a nerve using a special needle (typically known as a nerve block procedure).

2.1.2.6 In surgical wound applications, the wound would be closed, allowing the end of the catheter to remain within the wound.

2.1.2.7 The proximal end of the catheter may be attached to an infusion pump or it may be attached intermittently to a syringe for periodic injections of anesthetic drugs.

2.1.3 The catheter is suitable for use as an ambulatory device and is intended for use in hospitals, home environments or alternative care sites.

2.1.4 See Appendix A for drawings of the **Soaker Catheter**.

2.2 Product Configuration

See Appendix A for drawings/pictures and Appendix B for labeling.

2.2.1 The following **Soaker Catheter** models will be available:

2.2.1.1 S0605: 20 GA with 6.5 cm (2.5 in.) infusion segment (K991543).

2.2.1.2 S1205: 20 GA with 12.5 cm (5.0 in.) infusion segment.

2.2.2 The catheter is designed to be distributed in two basic configurations. See Appendix A, drawing number (b)(4)

2.2.2.1 Detail G of drawing (b)(4) depicts the proximal end of the catheter with a Touhy Borst type catheter connector.

2.2.2.2 An alternate configuration of the catheter connector may be a bonded/potted or insert molded luer lock connector.

2.2.2.3 Each of the catheter sizes will be available as a separate catheter with a currently marketed catheter connector (a Touhy Borst type is an example of any acceptable connector) or an attached luer lock connector. The connectors will meet the ANSI specifications conical connectors.

2.2.3 The **Soaker Catheter** may consist of a kit that includes components that are legally marketed (either pre-amendment devices or devices that have been granted permission to market via premarket notification regulation).

2.2.3.1 Examples of the kit components include the following:

2.2.3.1.1 Teleflex Medical (TFX) "T" peel catheter over needle 18 GA X 2 1/2" - 3 1/2" or

2.2.3.1.2 Johnson & Johnson Bioclusive dressing.

2.2.4 The **Soaker Catheter** may be used in I-Flow's Pain Management Systems such as K982946 and K984502.

2.3 Components and Materials

See Appendix D for data on the hollow fiber membrane.

2.3.1 Fluid path components:

2.3.1.1 Catheter: (b) (4)

2.3.1.2 Hollow Fiber Membrane: (Two Options)

(1) (b) (4)

(2) (b) (4)

3.0 OPERATIONAL SPECIFICATIONS AND DESCRIPTIONS

Test Conditions: (b) (4)

(b) (4)

3.1 Flow Rate Distribution Data:

(b) (4)

3.2 Flow Rate Comparative Data:

(b) (4)

3.3 Tensile Strength:

(b) (4)

51

3.3.1 (b) (4)
(b)(4)

3.4 Flexural Strength:

3.4.1 (b) (4)
(b)(4)

3.5 Elongation:

3.5.1 (b) (4)
(b)(4)

3.6 Attachment Security:

3.6.1 (b) (4)
(b)(4)

3.7 Hub Leakage:

3.7.1 (b) (4)
(b)(4)

3.8 Catheter Burst Pressure:

3.8.1 (b) (4)

3.8.2 (b)(4)

4.0 BIOLOGICAL SPECIFICATIONS

4.1 All materials in the catheter are identical in formulation to materials currently being used in other products with the same or similar uses and have a long history of use in those devices.

4.1.1 The hollow fiber membrane material is a common component used in various filter products such as infusion filters. See Appendix D for specification sheets of typical filter devices used with infusion sets and note the filter materials (b) (4) (b)(4)

4.2 I-Flow Corporation certifies that to the best of its knowledge that all materials are exactly the same as in legally marketed devices and the conditions of use are comparable.

- 4.3 Biological testing is in conformance with ISO 10993 Part 1 for fluid path components. See Appendix E for Biological Safety tests for hollow fiber material.
- 4.3.1 If there is a breakage of the catheter *in situ*, said break will not present a biocompatibility hazard.
- 4.4 Based on the requirements of ISO 10993-1 and FDA G95-1 Guidelines the catheter has been tested to and passed the following tests.
- 4.4.1 Cytotoxicity: In-vitro cytotoxicity testing (MEM elution method using L-929 mouse fibroblast cells).
- 4.4.2 Sensitization: Guinea Pig Maximization Tests Delayed Contact Sensitization Test (maximum method for biomaterial extracts).
- 4.4.3 Irritation: USP/ISO Intracutaneous Test
- 4.4.4 Systemic Toxicity: Acute systemic injection test
- 4.4.5 Hemolysis: In Vitro Rabbit Blood Determination
- 4.4.6 Subchronic Toxicity: Subacute toxicity test
- 4.4.7 Implantation: Rabbit implantation test
- 4.4.8 Pyrogenicity: Material medicated pyrogenicity
- 4.5 The **Soaker Catheter** is categorized as follows:
- 4.5.1 Device Category: Implant Device.
- 4.5.2 Body Contact: Tissue / Bone.
- 4.5.3 Contact Duration: Prolonged (24 hours to 30 days).

5.0 CHEMICAL AND DRUG SPECIFICATIONS

- 5.1 Drug Compatibility and Stability
- 5.1.1 There are no specific drugs referenced in the labeling for the **Soaker Catheter**.
- 5.1.2 The **Soaker Catheter** is intended for use with general local anesthetics and narcotic medications.
- 5.1.3 There are no drugs included in the **Soaker Catheter**.
- 5.1.4 The use of the hollow fiber membrane is not new to drug delivery. Most of the in-line filters used in infusion sets for drug delivery use this material as filter media. Virtually all I-Flow infusion sets utilize this technology, as do our competitors.

6.0 INTENDED USE

- 6.1 The **Soaker Catheter** is intended to be used as follows:
- 6.1.1 With I-Flow Corporation's PainBuster, ON-Q and Nerve Block pain management kits; and
- 6.1.2 As a stand alone device to provide continuous or intermittent delivery of local anesthetics or narcotics to surgical wound sites and/or close proximity to nerves outside of the epidural space. Routes of administration may be intraoperative, intramuscular, subcutaneous or percutaneous.

6.2 The catheter is single patient use only.

7.0 LABELS AND LABELING

7.1 I-Flow Corporation believes the proposed labels and labeling, where appropriate, meets the requirements of 21 CFR Part 801 as it relates to a determination of intended use and adequate directions for use.

7.2 The Directions for Use labeling:

7.2.1 Provides comprehensive directions for preparation and use.

7.2.2 Describes the routes of administration as it relates to intended use.

7.2.3 Contains warning information.

7.2.4 Contains the prescription statement required under 801.109 (b)(1).

7.2.5 Includes the specifications of the **Soaker Catheter**.

7.3 Packaging labels

7.3.1 Contains the prescription statement required under 801.109(b)(1).

7.4 Appendix G contains predicate labels and labeling

8.0 STANDARDS

8.1 There are currently no standards established for anesthetic catheters.

9.0 PACKAGING

9.1 The catheter is packaged in either a Tyvek pouch or a form/fill/seal tray.

9.2 Packaging is suitable for (b) (4) (b)(4)

9.3 Package aging tests have been conducted on the Tyvek pouch packaging material. The results of challenge testing have determined that the Tyvek pouches used to package the catheter maintains sterility in excess of three years.

10.0 STERILIZATION INFORMATION

10.1

10.2

10.3

10.4

(b) (4)

(b)(4)

11.0 COMPARISON TO LEGALLY MARKETED DEVICES

11.1 The **Soaker Catheter** is substantially equivalent to the (1) I-Flow IntraOp Catheter submitted in K991543, (2) Teleflex Medical (TFX) Epidural Catheter (K840202, originally submitted by Aries) (3) the B. Braun Perifix Set (K813186) and (4) the Epimed International FETH-R_KATH catheter.

11.2 Intended Use

11.2.1 The **Soaker Catheter** is intended to be used as follows:

11.2.1.1 With I-Flow Corporation's PainBuster, ON-Q and Nerve Block pain management kits; and

11.2.1.2 As a stand alone device to provide continuous or intermittent delivery of local anesthetics or narcotics to surgical wound sites and/or close proximity to nerves outside of the epidural space. Routes of administration may be intraoperative, intramuscular, subcutaneous or percutaneous.

11.2.2 (1) Teleflex Medical (TFX) Epidural Catheter (K840202, originally submitted by Aries) (2) the B. Braun Perifix Set (K813186) and (3) the Epimed International FETH-R_KATH catheter are intended to administer to a patient conduction, regional, or local anesthesia and specifically, administration of anesthetic into the epidural space.

11.3 Device Descriptions

11.3.1 Comparisons

11.3.1.1 This submission is intended to notify the Federal Food and Drug Administration that I-Flow Corporation intends to add an additional model to the family of **Soaker Catheters** formerly referred to as the IntraOp Catheter (K991543). The new model is virtually identical to the predicate 2.5 inch Soaker Catheter except that the new model will have a 5.0 inch infusion segment.

11.3.1.2 The device under review and its predicates are closed end with lateral/radial side holes.

11.3.1.3 All of the devices have the same or similar gauge sizes (approximately 20G).

11.3.1.4 The **Soaker Catheter** uses the TFX Epidural Catheter in its design. Both devices use nylon.

11.3.1.5 The B. Braun Perifix Set (including catheter connector) is used in the I-Flow PainBuster K980558 and K982946; Nerve Block K984502; Paragon Pain Management Kit K984146; and SideKick Pain Management kit K990425. The Braun catheter is identified in all of the name kits. (See Appendix C for I-Flow product labeling.) All of the kits has similar intended uses as **the Soaker Catheter**.

11.3.1.6 All the catheters provide a catheter connector device similar to a Touhy Borst connector or a molded luer lock connector.

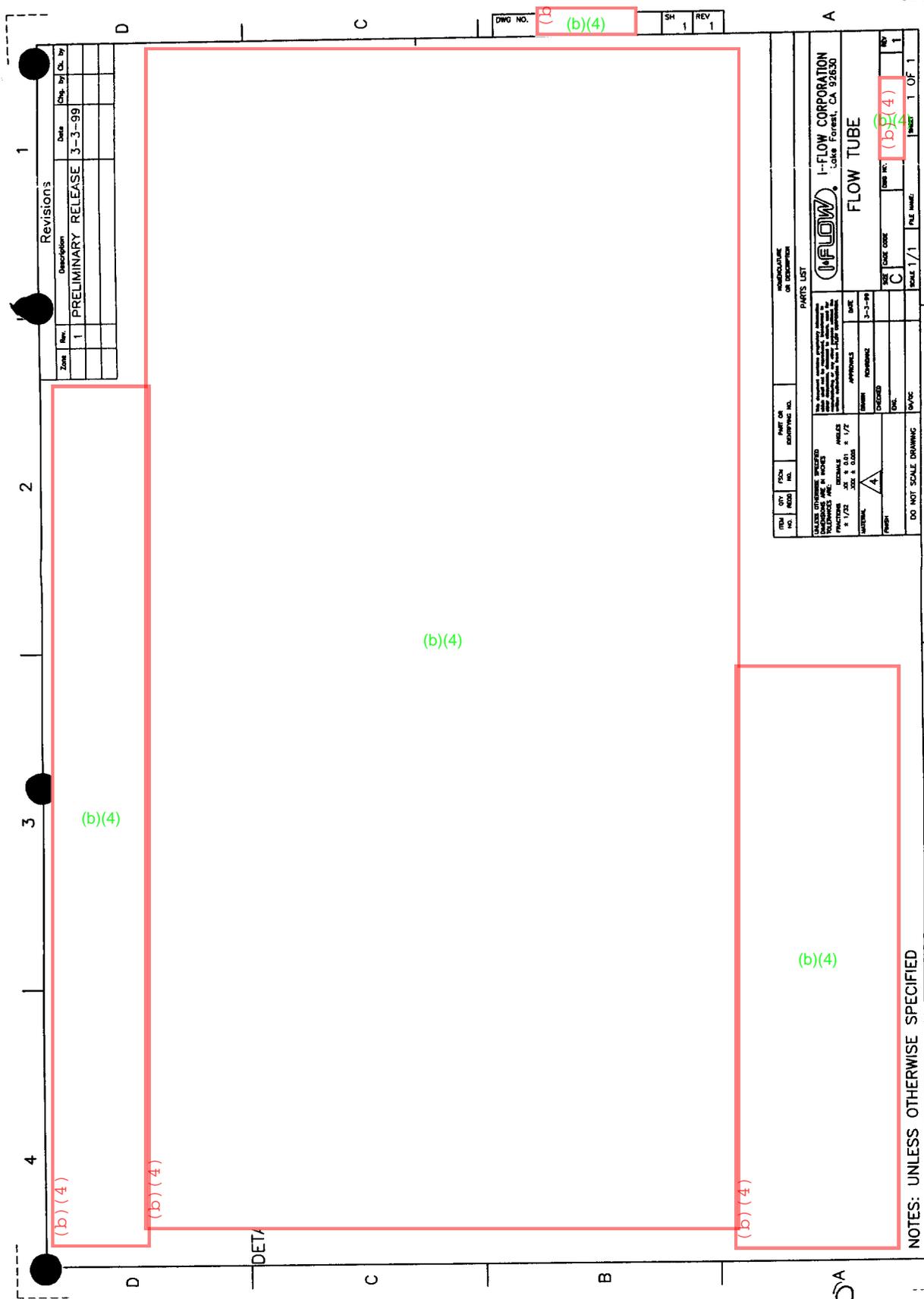


- 11.3.1.7 Flow Rate Performance Data: Flow rates through the **Soaker Catheter** were measured and tested against the B. Braun catheter. Flow rates from 0.5 to 200 ml/hr produced equal performance for the two catheters. With no reduction in flow.
- 11.3.1.8 Tensile strength: The tensile strength of the Intra Op Catheter and the B. Braun catheter were compared. Both devices survived pull tests where a pull force of 10 lbs was applied to the catheters. The TFX nylon produced slightly better performance.
- 11.3.2 Materials
 - 11.3.2.1 The **Soaker Catheter's** fluid path materials are in conformance with ISO 10993 Part 1.
- 11.3.3 Based upon the data presented in this section, I-Flow Corporation has determined that the **Soaker Catheter** is substantially equivalent to the named predicate devices.



Appendix A – Soaker Catheter Drawing





Zone	Rev.	Description	Date	Chg. by	Ch. by
	1	PRELIMINARY RELEASE	3-3-99		

DWG NO. (b)(4) SH 1 REV 1

MANUFACTURE OR DESCRIPTION
PARTS LIST

FLOW CORPORATION
 Lake Forest, CA 92630

FLOW TUBE

DATE: 3-3-99
 SCALE: 1/1
 SHEET: 1 OF 1

DO NOT SCALE DRAWING

88

NOTES: UNLESS OTHERWISE SPECIFIED

Appendix B – Soaker Catheter Labeling

59

Directions for Use

Ref. Nos. S0605; S1205

INDICATIONS FOR USE

The Soaker Catheter is intended to provide continuous or intermittent delivery of local anesthetics or narcotics to surgical wound sites and close proximity to nerves outside of the epidural space. Routes of administration include intraoperative, intramuscular, subcutaneous and percutaneous.

CAUTION

- Do not use if package has been opened or is damaged or if either protector cap is not in place. The Soaker Catheter is sterile and non-pyrogenic.
- Single patient use only. Do not resterilize.
- Do not withdraw catheter through needle because of the possible danger of shearing.
- Use only smooth-edged atraumatic clamps or forceps.
- Incompatible drug delivery may cause a precipitating reaction, which could result in an obstructed catheter.
- After use, this product may be a potential biohazard. Handle and discard in accordance with accepted medical practice.

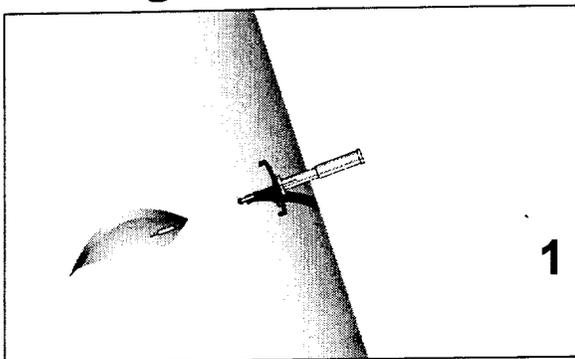
CONTRAINDICATIONS

The Soaker Catheter is not intended for intravenous, intra-arterial or epidural drug delivery. Skin surface or subsurface infection at or near proposed site of insertion.

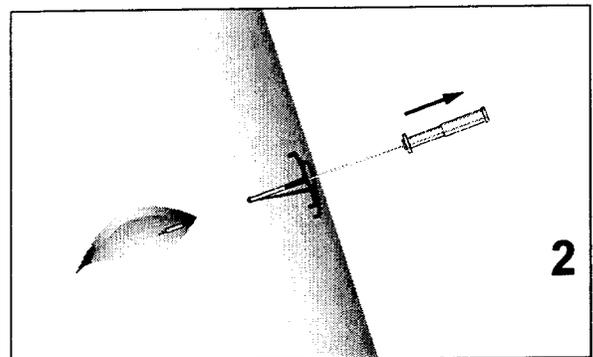
SUGGESTED CATHETER MAINTENANCE

The catheter should be maintained in accordance with standard hospital protocols.

Placing the Catheter



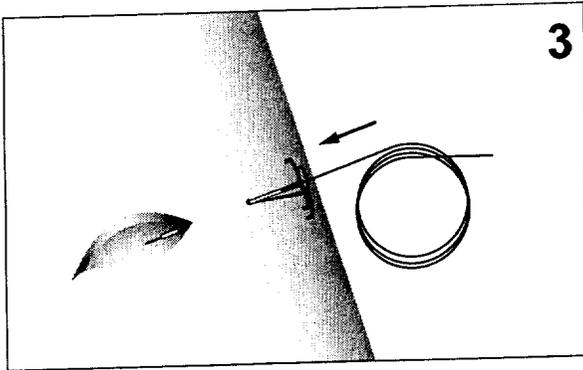
Insert introducer needle through the skin (approximately 3-5 cm away from wound site) then push introducer needle into the surgical wound site. Do not insert catheter past catheter sleeve.



Remove the needle from the introducer.

I-FLOW

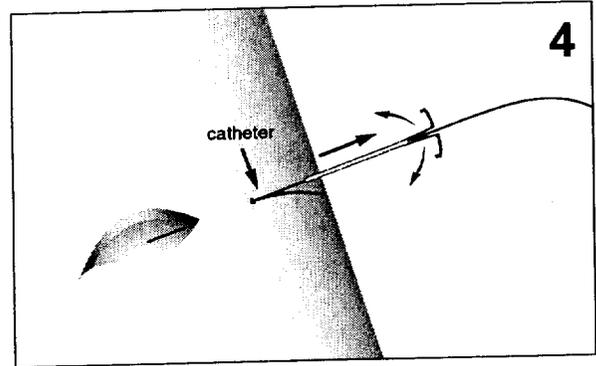
60



Insert the marked end of the catheter through the hub of the introducer into the wound site to desired depth.

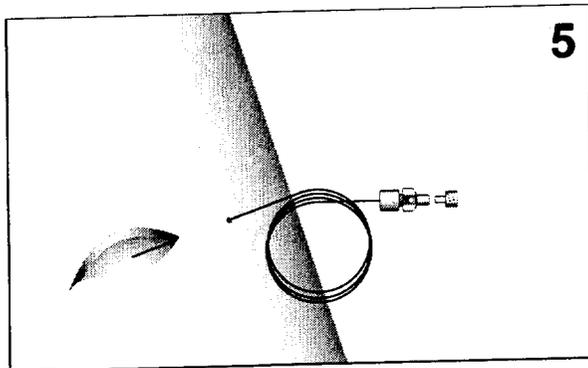
NOTE: Drug infusion occurs between catheter marking and marked tip.

CAUTION: Assure that the catheter tip is not in a vein or artery.



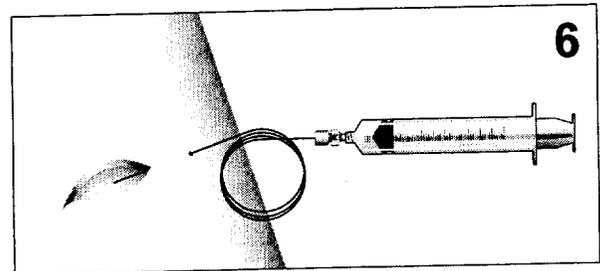
While holding catheter tightly in place, slide introducer needle out and peel away from catheter. Assure catheter placement in wound site.

NOTE: Catheter placement will vary depending on surgical procedure. Care should be taken during catheter placement to ensure that an occlusion will not occur during use and that catheter removal will not be impeded.



Attach the catheter connector to the unmarked end of the catheter. Tighten until catheter cannot be removed.

Catheter may need to be secured with tape to maintain catheter placement.



Attach syringe to catheter connector and prime catheter.

WARNING: If catheter tip location cannot be verified before priming, draw back on the syringe to check for blood return. Blood return may indicate the catheter is in a vein or artery which is contraindicated.

Removing the Catheter

Prompt removal of the catheter is advised after infusion is complete to reduce risk of infection. Do not use excessive force to remove catheter.

CAUTION

Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

For Customer Service
Call: 1.800.448.3569
949.206.2700
www.I-Flowcorp.com



European Representative:
MPS Medical Product Service GmbH
Borngasse 20, 35619 Braunfels, Germany

A PRODUCT OF



I-FLOW CORPORATION
LAKE FOREST, CA 92630
U.S.A.

U.S. and Foreign Patents Pending.

130XXXX
12/99

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CONTENU / CONTENIDO: 1



I-FLOW CORPORATION, LAKE FOREST, CA U.S.A. PART NO. 400XXXX

Soaker Catheter

20 GA x 63.5 cm (25 in.)
Closed Tip 6.5 cm (2.5 in.) Multi-Hole Distribution



STERILE



LOT

SEE DIRECTIONS FOR USE.
CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

Manufactured by / Hersteller von /
Fabrique par / Fabricado por:
I-Flow Corporation
Lake Forest, CA 92630 U.S.A.



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European Representative / Europäische Vertretung /
Représentant pour l'Europe / Representante Europeo:
MPS Medical Product Service GmbH
Borngasse 20, 35619 Braunfels, Germany

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62

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CONTENU / CONTENIDO: 1



I-FLOW CORPORATION, LAKE FOREST, CA U.S.A.

PART NO. 400XXXX

Soaker Catheter

20 GA x 63.5 cm (25 in.)
Closed Tip 12.5 cm (5.0 in.) Multi-Hole Distribution



STERILE



LOT

SEE DIRECTIONS FOR USE.
CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

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I-Flow Corporation
Lake Forest, CA 92630 U.S.A.



European Representative / Europäische Vertretung /
Représentant pour l'Europe / Representante Europeo:
MPS Medical Product Service GmbH
Borngasse 20, 35619 Braunfels, Germany

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I-FLOW CORPORATION, LAKE FOREST, CA U.S.A.

CONTENTS / INHALT / CONTENU / CONTENIDO: 10

REF S0605

PART NO. 500XXXXX

Soaker Catheter

20 GA x 63.5 cm (25 in.)

Closed Tip 6.5 cm (2.5 in.) Multi-Hole Distribution



STERILE



LOT

SEE DIRECTIONS FOR USE. CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

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Représentant pour l'Europe / Representante Europeo:
MPS Medical Product Service GmbH
Borngasse 20, 35619 Braunfels, Germany

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64

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I-FLOW CORPORATION, LAKE FOREST, CA U.S.A.

REF S1205

PART NO. 500XXXX

CONTENTS / INHALT / CONTENU / CONTENIDO: 10

Soaker Catheter

20 GA x 63.5 cm (25 in.)

Closed Tip 12.5 cm (5.0 in.) Multi-Hole Distribution



STERILE



LOT

SEE DIRECTIONS FOR USE. CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

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MPS Medical Product Service GmbH
Borngasse 20, 35619 Braunfels, Germany

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65

ON-QTM SoakerTM Catheter

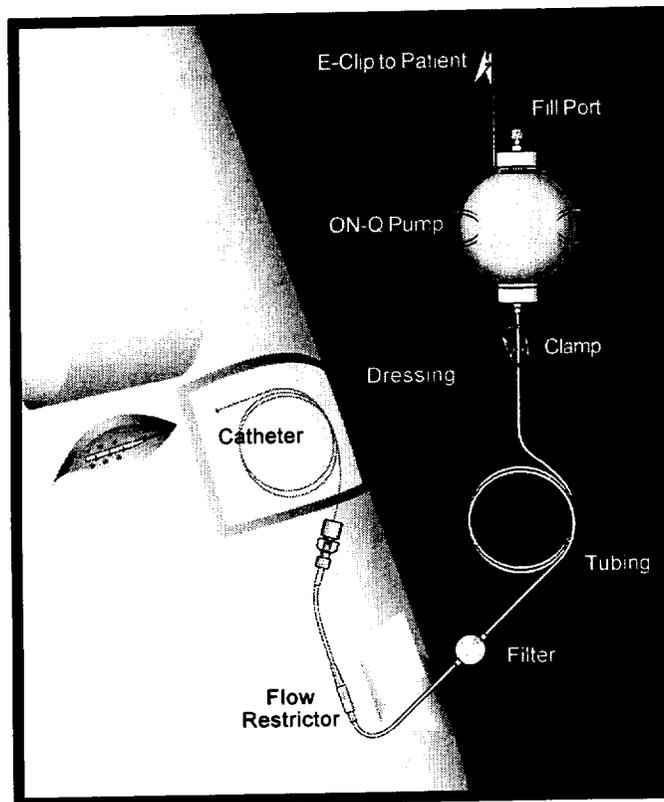
Pain Management System

CONTENTS

- 1 each - ON-Q Infusion Pump
- 1 each - Split Introducer Needle
- 1 each - 20 GA Soaker Catheter
- 1 each - Latex Free Syringe
- 1 each - Dressing
- 1 each - Medication Label
- 1 each - E-Clip and/or Carry Case

DESCRIPTION

The ON-Q Pain Management System is intended to provide continuous infusion of a local anesthetic directly into an intraoperative site for postoperative pain management. Infusions may also be administered subcutaneously.



**DO NOT USE IF PACKAGE HAS BEEN OPENED, IS DAMAGED OR IF EITHER PROTECTOR CAP IS NOT IN PLACE.
THE ON-Q SYSTEM IS STERILE AND NON-PYROGENIC.
SINGLE PATIENT USE ONLY. DO NOT RESTERILIZE.**

CAUTION

Do not exceed maximum fill volume of pump.

Do not withdraw catheter through needle because of the possible danger of shearing.

Use only smooth-edged atraumatic clamps or forceps.

Medications used with this system should be administered in accordance with instructions provided by the drug manufacturer.

After use, this product may be a potential biohazard. Handle and discard in accordance with accepted medical practice.

Prompt removal of the catheter is advised after infusion is complete to reduce risk of infection.

CONTRAINDICATIONS

The Soaker Catheter is not intended for intravenous, intra-arterial or epidural drug delivery.

The ON-Q is not intended for the delivery of blood, blood products, lipids or fat emulsions.

SUGGESTED CATHETER MAINTENANCE

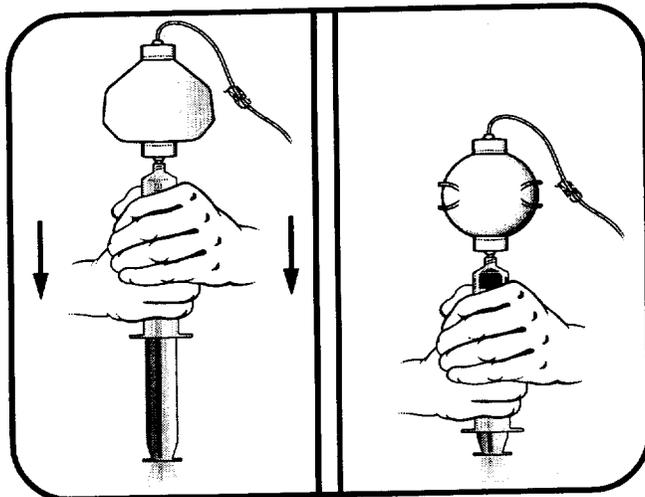
The catheter should be maintained in accordance with standard hospital protocols.

DIRECTIONS FOR USE

Use Aseptic Technique

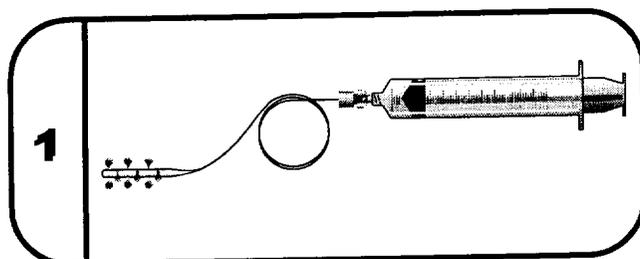
Filling the ON-Q Pump

- Close clamp on tubing.
- Remove protective cap from fill port. Do not discard cap.
- Attach filled syringe to the fill port and inject fluid into pump (refer to diagram below). Repeat as necessary.
- Do not exceed maximum fill volume (refer to table on last page for applicable fill volumes).
- Replace fill port cap.
- Label with the appropriate pharmaceutical and patient information.
- Open the clamp and remove the distal end cap to prime the pump (up to 15 minutes). Allow the medication to fill the entire tubing and luer connector. When all air has been removed from the tubing and connector close the clamp until ready to use.



Priming The Catheter

Proper priming of the catheter and pump tubing is very important. Any trapped air in the catheter may create air locks which may affect proper catheter performance.



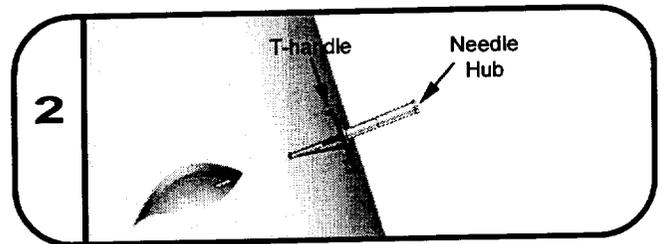
Attach a syringe filled with medication to the catheter connector. Slowly prime the catheter until medication infuses out all the holes along the length of the catheter. Make sure no air is trapped in the catheter.

Placing the Catheter

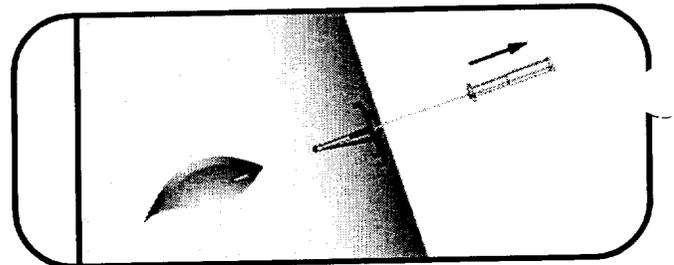
NOTE: Remove needle guard from the introducer while holding T-handle.

Do not apply excessive pressure to the T-handle.

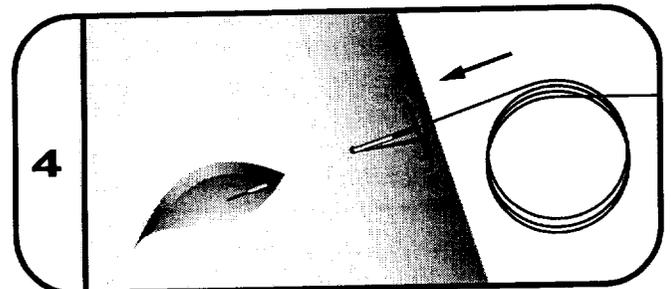
Grip only the needle hub during insertion.



Insert introducer needle (with bevel up) through the skin (approximately 3-5 cm away from wound site) then push introducer needle into the surgical wound site.



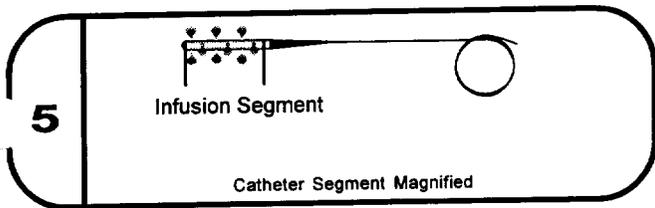
While holding the T-handle, withdraw the introducer needle.



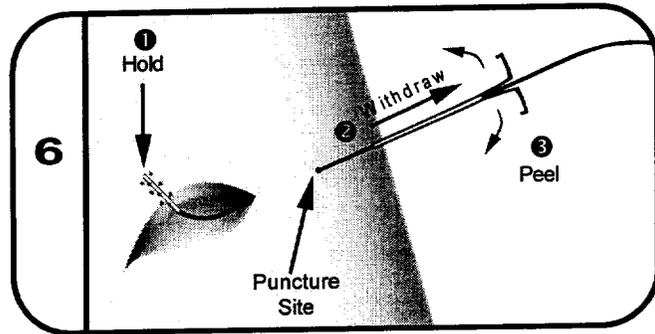
Insert the marked end of the catheter through the opening of the T-handle introducer into the wound site.

WARNING: Assure that the catheter tip is not in a vein or artery.

NOTE: Catheter placement will vary depending on surgical procedure. Care should be taken during catheter placement to ensure that occlusion will not occur during use and that catheter removal will not be impeded.



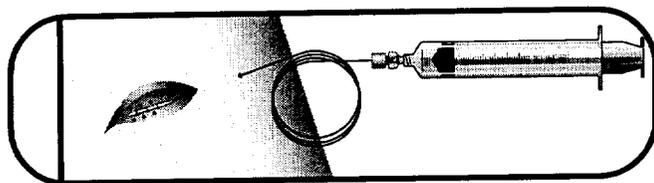
Drug infusion occurs between catheter marking and marked tip.



Advance catheter into wound site until white catheter segment is visible.

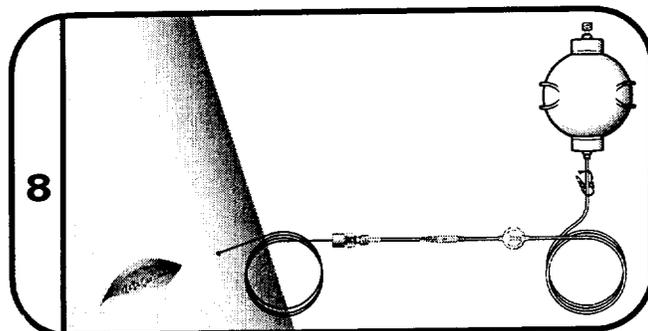
While holding catheter tip ① withdraw T-handle from puncture site ② and split the introducer sheath and peel it away from the catheter ③.

Place the catheter within wound site to desired position.

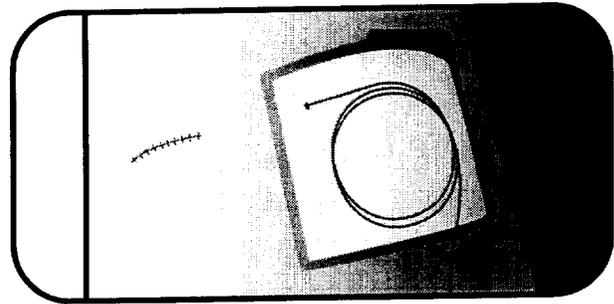


WARNING: If catheter tip location cannot be verified before priming, draw back on the syringe to check for blood return. Blood return may indicate the catheter is in a vein or artery which is unsafe (contraindicated).

Attach syringe to catheter connector and prime catheter with local anesthetic.



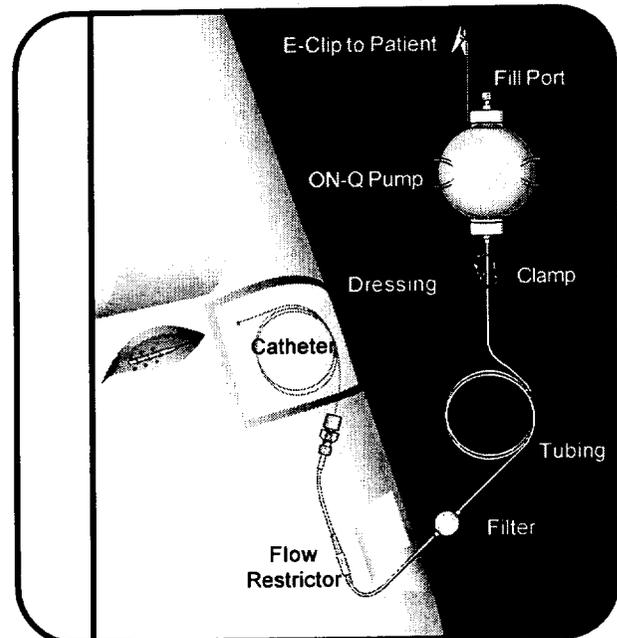
Attach the catheter connector to the pump tubing. Open the pump clamp to begin infusion.



Secure catheter by coiling close to the insertion site. Apply dressing while holding the corner next to the blue tab, pull the blue tab to remove center backing from dressing.

Apply dressing over insertion site and coiled catheter, keeping separate from wound.

Remove dressing frame by pulling a corner. Assure that the edges of the dressing are adequately sealed.



Secure flow restrictor to skin. The flow restrictor must not be in contact with cold therapy pads.

The ON-Q system may contain an E-Clip and/or Carry Case. If using the E-Clip, attach to the top of the pump. Secure the ON-Q pump with the E-Clip or Carry Case.

Infusion is complete when the ON-Q pump is no longer inflated.

68

Delivery Time Information for the ON-Q Pain Management System

		PM011	PM012	PM013	PM014
NOMINAL FLOW RATE (ml/hr)		0.5	2	2	5
NOMINAL FILL VOLUME (ml)		65	100	270	270
MAXIMUM FILL VOLUME (ml)		65	125	335	335
RETAINED VOLUME (ml)		≤ 3	≤ 4	≤ 9	≤ 9
APPROXIMATE DELIVERY TIME		FILL VOLUME (ml)			
12 hours	0.5 days		35		
18 hours	0.75 days		50		
24 hours	1.0 days		65		150
48 hours	2.0 days	35	100		255
60 hours	2.5 days	40	125		290
72 hours	3.0 days	45		175	330
96 hours	4.0 days	55		215	
120 hours	5.0 days	65		250	

Delivery accuracy is $\pm 15\%$ (at a 95% confidence interval) of the labeled infusion rate when delivering normal saline at 88° F (31°C) against a back pressure of 40 cm of water.

NOTES:

1. The nominal infusion rate and fill volume for each ON-Q pump is labeled on the fill port.
2. Actual infusion times may vary due to:
 - viscosity and/or drug concentration.
 - positioning the ON-Q pump above (time decreases) or below (time increases) the catheter site.
 - temperature: the ON-Q flow restrictor (located distal to the filter) should be close to, or in direct contact with, the skin (88°F/31°C). Temperature will affect solution viscosity, resulting in shorter or longer delivery time. If the ON-Q is used with the flow restrictor at room temperature (68°F/20°C), delivery time may increase by approximately 25%.
3. This product uses DEHP plasticized PVC. Certain solutions may be incompatible with the PVC material used in the administration set. Consult the drug package insert and other available sources of information for a more thorough understanding of possible incompatibility problems.

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

U.S. Patents: D324,911; 5,080,652; 5,284,481. U.S. and Foreign Patents Pending.

For Customer Service
Call: 1.800.873.3636



European Representative:
MPS Medical Product Service GmbH
Borgasse 20, 35619 Braunfels, Germany



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LAKE FOREST, CA 92630
U.S.A.

Appendix C – Predicate Labeling

IntraOp Catheter

Directions for Use

Ref. Nos. IOC0205; IOC0500
IOC0705; IOC1000

INDICATIONS FOR USE

The IntraOp Catheter is designed for placement in the intraoperative site for infusing local anesthetic. For use with peel away needle or split catheter introducer. The catheter has been tested for flow rates of 0.5 ml/hr to 200 ml/hr. Flow rates outside this range may not meet performance specifications.

CAUTION

Do not use if package has been opened or is damaged or if either protector cap is not in place. The IntraOp Catheter is sterile and non-pyrogenic.

Single patient use only. Do not resterilize.

Do not withdraw catheter through needle because of the possible danger of shearing.

Use only smooth-edged atraumatic clamps or forceps.

Incompatible drug delivery may cause a precipitating reaction, which could result in an obstructed catheter.

After use, this product may be a potential biohazard. Handle and discard in accordance with accepted medical practice.

CONTRAINDICATIONS

The IntraOp Catheter is not intended for intravenous, intra-arterial or epidural drug delivery.

Skin surface or subsurface infection at or near proposed site of insertion.

The patient is known or is suspected to be allergic to materials contained in device.

POSSIBLE COMPLICATIONS

Catheter occlusion

Catheter fragmentation

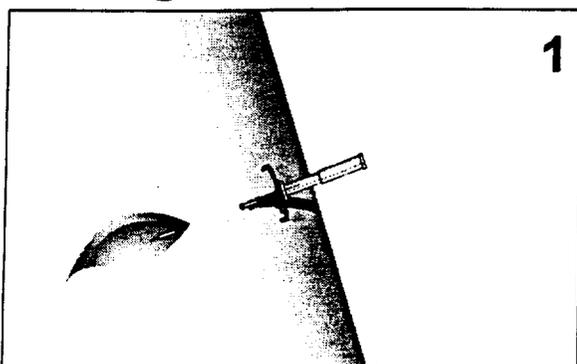
Catheter rupture

Infection/bacteremia/sepsis

SUGGESTED CATHETER MAINTENANCE

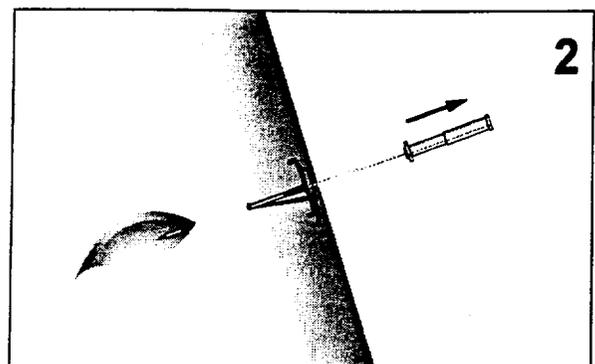
The catheter should be maintained in accordance with standard hospital protocols.

Placing the Catheter



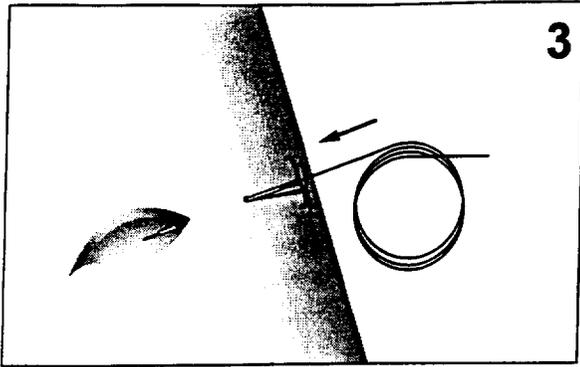
Insert introducer needle through the skin (approximately 3-5 cm away from wound site) then push introducer needle into the surgical wound site.

Do not insert catheter past catheter sleeve.



Remove the needle from the introducer.

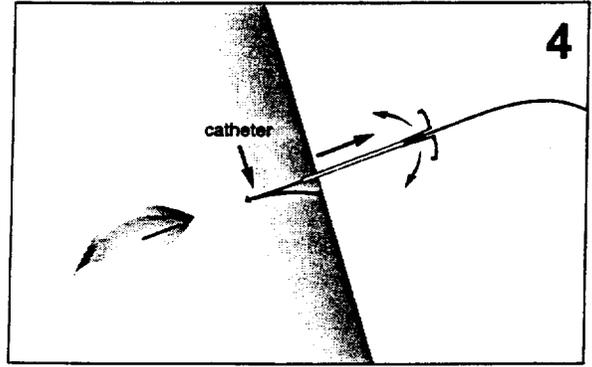
I·FLOW



Insert the marked end of the catheter through the hub of the introducer into the wound site to desired depth.

NOTE: Drug infusion occurs between catheter marking and marked tip.

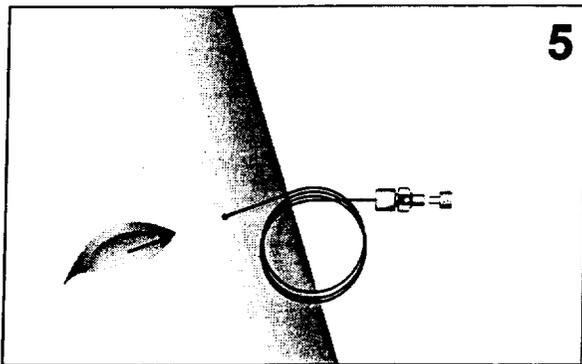
CAUTION: Assure that the catheter tip is not in a vein or artery.



While holding catheter tightly in place, slide introducer needle out and peel away from catheter. Assure catheter placement in wound site.

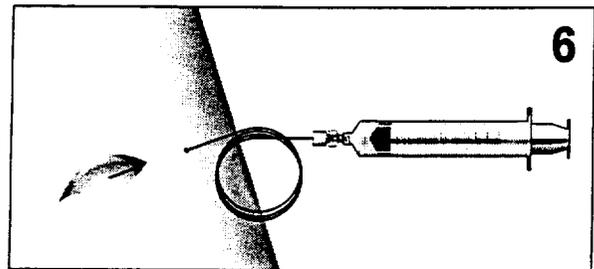
NOTE: Catheter placement will vary depending on surgical procedure. Care should be taken during catheter placement such that occlusion will not occur during use and that catheter removal will not be impeded.

Do not use excessive force to remove catheter.



Attach the catheter connector to the unmarked end of the catheter. Tighten until catheter cannot be removed.

Catheter may need to be secured with tape to maintain catheter placement.



Attach syringe to catheter connector and prime catheter.

WARNING: If catheter tip location cannot be verified before priming, draw back on the syringe to check for blood return. Blood return may indicate the catheter is in a vein or artery which is unsafe.

CAUTION

Federal (U.S.A.) law restricts this device to sale by or on the order of a physician. Prompt removal of the catheter is advised after infusion is complete to reduce risk of infection.

U.S. and Foreign Patents Pending.

For Customer Service
Call: 1.800.448.3569
949.206.2700
www.I-Flowcorp.com



European Representative:
MPS Medical Product Service GmbH
Borngasse 20, 35619 Braunfels, Germany

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1302342A
4/99

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CONTENU / CONTENIDO: 1



I-FLOW CORPORATION, LAKE FOREST, CA U.S.A. PART NO. 400XXXX

IntraOp Catheter

20GA x 63.5 cm (25 in.)
Closed Tip 6.35 cm (2.5 in.) Multi-Hole Distribution



STERILE



LOT

SEE DIRECTIONS FOR USE.
CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

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Fabrique par / Fabricado por:
I-Flow Corporation
Lake Forest, CA 92630 U.S.A.



European Representative / Europäische Vertretung /
Représentant pour l'Europe / Representante Europeo:
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Borngasse 20, 35619 Braunfels, Germany

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73

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REF IOC0205

I-FLOW CORPORATION, LAKE FOREST, CA U.S.A.

PART NO. 500XXXX

CONTENTS / INHALT / CONTENU / CONTENIDO: 10

IntraOp Catheter

20GA x 63.5 cm (25 in.)

Closed Tip 6.35 cm (2.5 in.) Multi-Hole Distribution



STERILE



LOT

SEE DIRECTIONS FOR USE. CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

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Représentant pour l'Europe / Representante Europeo:
MPS Medical Product Service GmbH
Borngasse 20, 35619 Braunfels, Germany

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34

PEEL OPEN

PEEL OPEN

PERIFIX PERIFIX PERIFIX

PERIFIX® Epidural Catheter Set

PRODUCT CODE
EC20-C
333530

Contents of unopened, undamaged package are:

STERILE

DISPOSABLE - Destroy after single use. Do not clean or resterilize. Store at controlled room temperature.

CONTENTS:

- One - Marked 20 GA. x 39.3 in. (100 cm) Radiopaque Polyamide Epidural Catheter with Closed Tip and Three Lateral Sideports
- One - Catheter Threading Assist Guide
- One - Screw Cap Luer Lock Catheter Connector

B | BRAUN

B. Braun Medical Inc.
Bethlehem, PA 18018
Assembled and packaged in U.S.A.
Components made in U.S.A. and Germany

CAUTION: Federal (U.S.A.) Law restricts this device to sale by or on the order of a physician.

P-2880

REV. 3/95

891430 EXP 1/02

75

PERIFIX® Epidural Catheter Directions

Contents of unopened, undamaged package are:

STERILE

DISPOSABLE - Destroy after single use. Do not clean or re-sterilize.

Store at controlled room temperature.

CAUTION: Federal (U.S.A.) Law restricts this device to sale by or on the order of a physician.

DIRECTIONS: Use Aseptic Technique.

Following puncture and verification of the Epidural Space, introduce the catheter tip through the Epidural Needle using the:

(1) Threading Assist Guide. The guide will increase longitudinal stability of the catheter.



CAUTION: DO NOT WITHDRAW CATHETER THROUGH NEEDLE BECAUSE OF THE POSSIBLE DANGER OF SHEARING.

Insert catheter to desired depth. Catheter markings: 5.5 cm (1 ring), 10.5 cm (2 rings), 15.5 cm (3 rings) in 1 cm increments, 20.5 cm (4 rings). The solid wide warning mark indicates exit of catheter from needle when using the Threading Assist Guide and a PERIFIX® Epidural Needle. The catheter will exit 1 cm before

the warning mark when not using the Threading Assist Guide.

Remove needle and Threading Assist Guide over catheter while holding catheter tightly in place.



(2) Introduce distal end of catheter as far as possible in central opening of transparent screw cap of catheter connector.



(3) Tighten screw cap until catheter can no longer be withdrawn. Administer test dose. Administer anesthetic as needed.

B | BRAUN

B. Braun Medical Inc.
Bethlehem, PA 18018

A4806076

P-3050

REV. 8/95

76

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CONTENU / CONTENIDO: 1



I-FLOW CORPORATION, LAKE FOREST, CA U.S.A.

REF NB060020
PART NO. 500XXXX

NERVE BLOCK INFUSION KIT 60 ml Vol x 2 ml/hr

CONTENTS: 1 each - 60 ml Vol, 2 ml/hr Pump
1 each - 18 Ga x 2 Inch Touhy Needle
1 each - 20 Ga Epidural Catheter Set
1 each - 60 ml Syringe
1 each - Transparent Dressing
1 each - Hemostasis Valve Assembly
1 each - Hookup Wire

PACKAGE IS NOT STERILE.
INDIVIDUAL COMPONENTS
ARE STERILE PACKAGED.



LOT

SEE DIRECTIONS FOR USE

CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A HEALTHCARE PROFESSIONAL.

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Fabrique par / Fabricado por:
I-Flow Corporation
Lake Forest, CA 92630 U.S.A.

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0123

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Représentant pour l'Europe / Representante Europeo:
MPS Medical Product Service GmbH
Bomgasse 20, 35619 Braunfels, Germany

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CONTENTS / INHALT /
CONTENU / CONTENIDO: 1



I-FLOW CORPORATION, LAKE FOREST, CA U.S.A.

REF NB065005
PART NO. 500XXXX

NERVE BLOCK INFUSION KIT 65 ml Vol x 0.5 ml/hr

CONTENTS: 1 each - 65 ml Vol, 0.5 ml/hr Pump
1 each - 18 Ga x 2 Inch Touhy Needle
1 each - 20 Ga Epidural Catheter Set
1 each - 60 ml Syringe
1 each - Transparent Dressing
1 each - Hemostasis Valve Assembly
1 each - Hookup Wire

PACKAGE IS NOT STERILE.
INDIVIDUAL COMPONENTS
ARE STERILE PACKAGED.



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SEE DIRECTIONS FOR USE

CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A HEALTHCARE PROFESSIONAL.

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CONTENU / CONTENIDO: 1



REF PG100020

I-FLOW CORPORATION, LAKE FOREST, CA U.S.A.

PART NO. 5001202

PARAGON INFUSION KIT 100 ml Vol x 2 ml/hr

CONTENTS: 1 each - 100 ml Vol, 2 ml/hr Administration Set
1 each - 16GA I.V. Catheter Needle
1 each - 20GA Epidural Catheter Set
1 each - 60cc Syringe
1 each - Transparent Dressing

PACKAGE IS NOT STERILE.
INDIVIDUAL COMPONENTS
ARE STERILE PACKAGED.



LOT

SEE DIRECTIONS FOR USE

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CONTENTS / INHALT /
CONTENU / CONTENIDO: 1



REF PG100040

I-FLOW CORPORATION, LAKE FOREST, CA U.S.A.

PART NO. 5001203

PARAGON INFUSION KIT 100 ml Vol x 4 ml/hr

CONTENTS: 1 each - 100 ml Vol, 4 ml/hr Administration Set
1 each - 16GA I.V. Catheter Needle
1 each - 20GA Epidural Catheter Set
1 each - 60cc Syringe
1 each - Transparent Dressing

PACKAGE IS NOT STERILE.
INDIVIDUAL COMPONENTS
ARE STERILE PACKAGED.



LOT

SEE DIRECTIONS FOR USE

CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A HEALTHCARE PROFESSIONAL.

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78

SIDEKICK™

PAIN MANAGEMENT SYSTEM

The SideKick Pain Management System includes the SideKick Pain Management Kit and SideKick Infusion Pump. The kit is designed to work with the infusion pump, which may be sold separately.

KIT CONTENTS

- 1 each - Administration Set (package sterile)
- 1 each - 16 GA I.V. Catheter Needle (package sterile)
- 1 each - 20 GA Epidural Catheter Set (package sterile)
- 1 each - Medication Label (non-sterile)
- 1 each - Carrying Case (non-sterile)

INTENDED USE

The SideKick Pain Management System is intended to provide a continuous infusion of a local anesthetic directly into an intraoperative site for postoperative pain management. Additional routes of administration include subcutaneous, intramuscular and epidural.

DO NOT USE IF PACKAGE HAS BEEN OPENED OR IS DAMAGED OR IF EITHER PROTECTOR CAP IS NOT IN PLACE.

SIDEKICK KIT IS SINGLE PATIENT USE ONLY.

SIDEKICK INFUSION PUMP IS REUSABLE AND NON-STERILE. DO NOT STERILIZE. REFER TO CARE OF THE SIDEKICK INFUSION PUMP.

CONTRAINDICATIONS

Not for intravenous or intra-arterial drug delivery.
Not for blood, blood products, lipids or fat emulsions delivery.

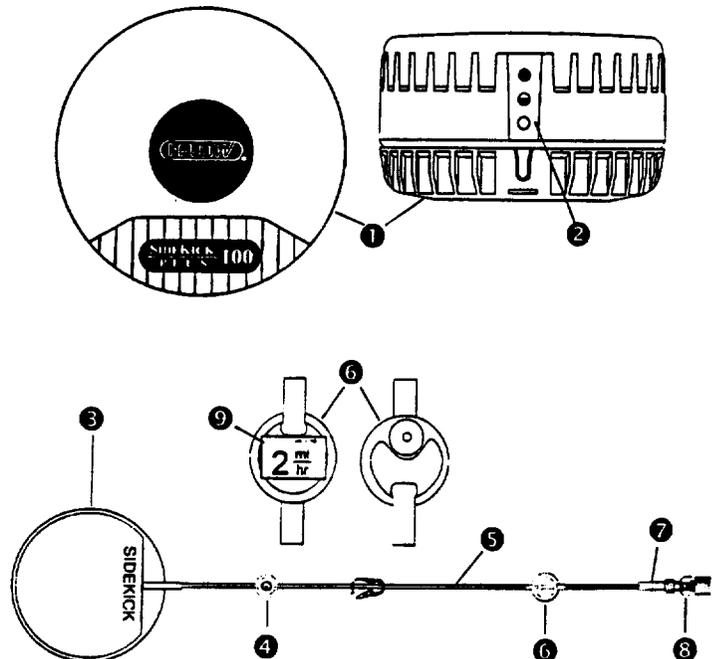
CAUTION

1. Medications used with this system should be administered in accordance with instructions provided from the drug manufacturer.
2. This product contains natural rubber latex which may cause allergic reactions. Individuals with known natural rubber latex sensitivities should not use this product.

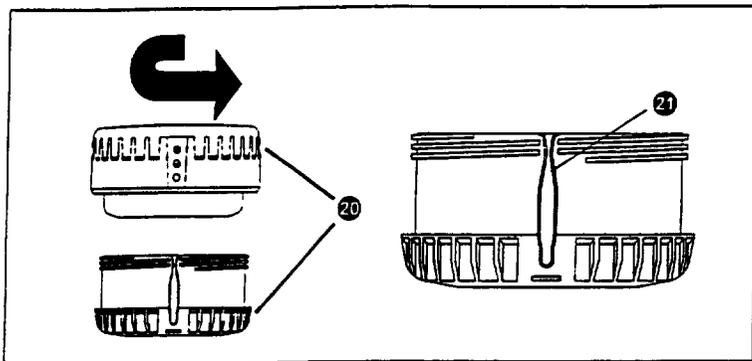
THE SIDEKICK PAIN MANAGEMENT INFUSION PUMP AND ADMINISTRATION SET

DESCRIPTION

1. SIDEKICK Infusion Pump ①
2. Fluid Level Indicator ②
3. Reservoir Bag ③
4. Fill Port ④
5. PVC Tubing (approx. 127 cm) ⑤
6. 1.2 micron air-eliminating filter ⑥
7. Flow restrictor ⑦
8. Luer Lock ⑧
9. Flow Rate Label ⑨



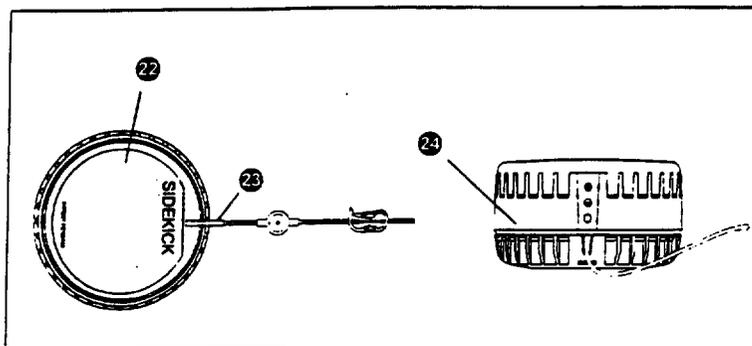
DIRECTIONS FOR USE



LOADING THE RESERVOIR BAG INTO THE SIDEKICK INFUSION PUMP

CAUTION: Infusion pump, carrying case and medication label are NON-STERILE. Not to be loaded in sterile field.

1. Twist open the top and bottom halves of the infusion pump. 20
2. Before placing the reservoir bag into the infusion pump, slide the thin portion of the administration set through the slot found on the bottom of the pump. 21
3. Center the bag in the bottom and press all around the edge of the bag to fully seat the bag in the bottom. Make sure there are no wrinkles in the bag. 22
4. Pull gently on the thick portion of the tubing so that it is fully extended and seated at the bottom of the slot. 23
5. Twist the top and bottom halves of the infusion pump together until they meet. 24

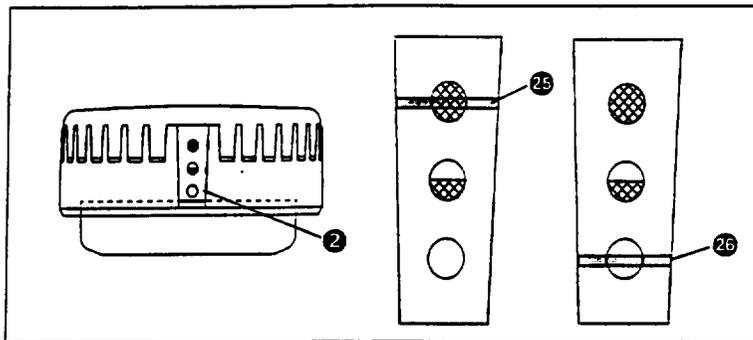


STARTING THE INFUSION

1. Start the infusion by opening the clamp on the administration set.
2. Place the infusion pump in the carrying case. The carrying case can be worn on a belt, over the shoulder, or around the waist.

THE FLUID LEVEL INDICATOR

1. The window with the markings on the side of the infusion pump is used to estimate how far the infusion has progressed. 2
2. When the reservoir bag is filled to 100 ml, the top of the pressure plate will be aligned with the top round marker. 25
3. As the infusion progresses, the plate will move to the bottom marker indicating the bag is nearly empty. 26



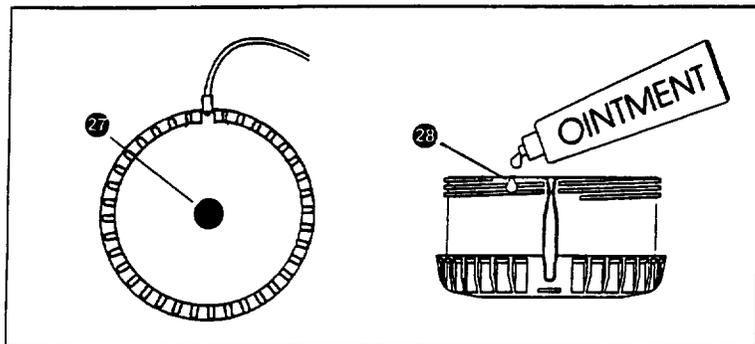
THE END OF THE INFUSION

The infusion is complete when a large blue dot appears through the bottom of the infusion pump. 27

CARE AND CLEANING OF THE SIDEKICK INFUSION PUMP

The SIDEKICK infusion pump is durable and is intended to be used for repeated drug deliveries. After each patient use, the exposed surfaces, except the threads, may be wiped clean using isopropyl alcohol or a 10% bleach solution.

NOTE: Do not submerge the infusion pump in a bleach solution. After cleaning, if the infusion pump is difficult to twist together, place a small drop of lubricating ointment (such as K-Y® Jelly) on a small section of the threads on the bottom of the infuser. Twist the top of the infuser onto the bottom to spread out the ointment. 28



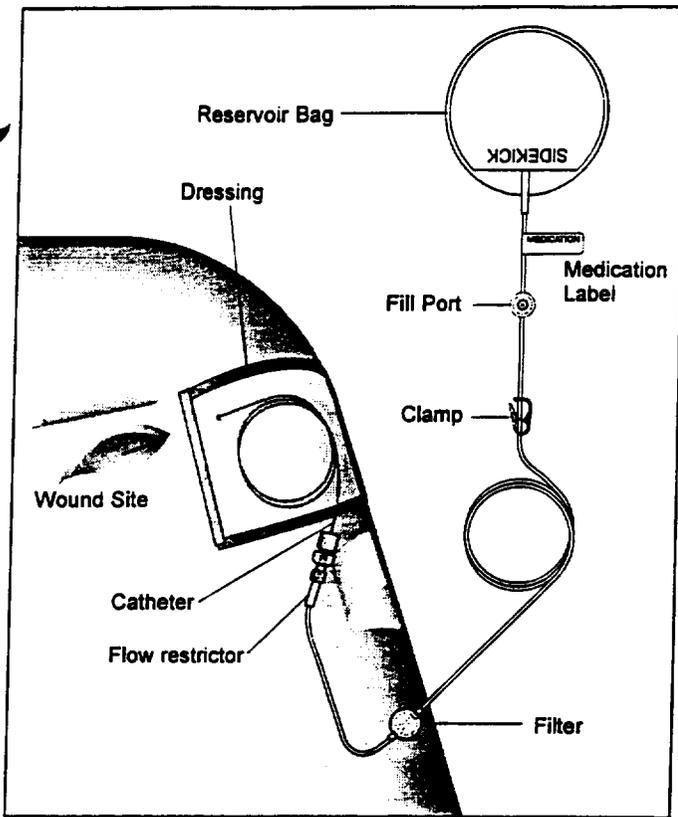
IMPORTANT

Only SIDEKICK administration sets are authorized for use with this product. I-Flow Corporation accepts no responsibility for performance, or the liability for damages, caused by the misuse of this product when used with unauthorized administration sets.

This product uses DEHP plasticized PVC. Certain solutions may be incompatible with the PVC material used in the administration set. Consult the drug package insert and other available sources of information for a more thorough understanding of possible incompatibility problems.

81

DIRECTIONS FOR USE



The SIDEKICK Infusion Pump Specifications

Delivery Accuracy: $\pm 15\%$ at 95% confidence interval.

Priming volume: Allow 1 ml for loss during priming.

NOTES

- The infusion rates for each administration set are indicated on the administration set label on the filter.
- Actual infusion rates may vary from the specified range due to:
 - viscosity and/or drug concentration.
 - temperatures above or below the operating conditions.
 - the positioning of the infusion pump above or below the infusion site.
- The SIDEKICK System has been calibrated using Normal Saline as the diluent and skin contact temperature (32°C, 90°F) as the operating environment. When using Normal Saline and skin temperature the SIDEKICK System will flow at the specified nominal rate. The use of other diluents or operating temperatures other than the above will affect the nominal flow rate.

DELIVERY TIME INFORMATION FOR SIDEKICK

NOMINAL FLOW RATE (ml/hr)		100 ml Vol x 2 ml/hr pump	
		2	
NOMINAL VOLUME (ml)		100	
MAXIMUM VOLUME (ml)		110	
RETAINED VOLUME (ml)		≤5	
APPROXIMATE DELIVERY TIME		FILL VOLUME (ml)	
12 hours		25	
18 hours		38	
24 hours	1 day	50	
48 hours	2 days	100	

CAUTION

Federal (U.S.A.) law restricts this device to sale by or on the order of a healthcare professional. Prompt removal of the catheter is advised after infusion is complete to reduce risk of infection.

For Customer Service
 Call: 1.800.448.3569
 949.206.2700
www.i-flowcorp.com

CE European Representative:
 MPS Medical Product Service GmbH
 0123 Borngasse 20, 35619 Braunfels, Germany

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 LAKE FOREST, CA 92630
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Appendix D – Hollow Fiber Material Sheets

83

Pages 94 through 95 redacted for the following reasons:

CCI, b4

Appendix E – Biological Safety Tests of Hollow Fiber

Sp

Pages 98 through 99 redacted for the following reasons:

CCI, b4

I-Flow Corporation

MEMORANDUM

November 29, 1999

To: LETTER TO FILE

(b)(4)

(b)(4)

90

Appendix F – Summary of Safety and Effectiveness

Summary of Safety and Effectiveness

Trade Name: **Soaker Catheter**

Common Name: Anesthetic Catheter

Classification Name: Anesthesia Conduction Catheter

Classification Panel: Anesthesiology

All questions and/or comments concerning this document should be made to:

Stanley E. Fry
Vice President of Regulatory and Quality

I-Flow Corporation
20202 Windrow Drive
Lake Forest, CA 92630

Telephone: 949.206.2700
Fax: 949.206.2600

1.0 GENERAL INFORMATION

1.1 Statement of Equivalence

- 1.1.1 The **Soaker Catheter** is substantially equivalent to the (1) I-Flow IntraOp Catheter (K991543), (2) Teleflex Medical (TFX) Epidural Catheter (K840202, originally submitted by Aries), (3) B. Braun Perfifix Set (K813186) and (4) the Epimed International FETH-R_KATH catheter (K981329).
- 1.1.2 The **Soaker Catheter** package may include components that are legally marketed (either pre-amendment devices or devices that have been granted permission to market via premarket notification regulation) such as an introducer needle or dressing.

2.0 PHYSICAL SPECIFICATIONS AND DESCRIPTIONS

2.1 Description of the **Soaker Catheter**

- 2.1.1 The **Soaker Catheter** is identical to the predicate IntraOp Catheter (K991543). This premarket notification adds an additional model to the Soaker Catheter family of catheters.
- 2.1.2 The **Soaker Catheter** consists of a Teleflex Medical (TFX) Epidural Catheter (K840202, originally submitted by Aries Medical) with the insertion of a hollow fiber membrane in the inner diameter of the distal end of the catheter.
 - 2.1.2.1 The catheter has a closed end tip with multiple holes arranged radially along the lateral surface at the distal end of the device.

92

2.2 Product Configuration

2.2.1 The following **Soaker Catheter** models will be available:

2.2.1.1 S0605: 20 GA with 6.5 cm (2.5 in.) infusion segment (K991543).

2.2.1.2 S1205: 20 GA with 12.5 cm (5.0 in.) infusion segment.

2.2.1.3 Each of the catheter sizes will be available as a separate catheter with a currently marketed catheter connector (a Touhy Borst type is an example of any acceptable connector) or an attached luer lock connector. The connectors will meet the ANSI specifications conical connectors.

2.2.2 The **Soaker Catheter** may consist of a kit that includes components that are legally marketed (either pre-amendment devices or devices that have been granted permission to market via premarket notification regulation).

2.2.2.1 Examples of the kit components include the following:

2.2.2.1.1 Teleflex Medical (TFX) "T" peel catheter over needle 18 GA X 2 1/2" - 3 1/2" or

2.2.2.1.2 Johnson & Johnson Bioclusive dressing.

2.2.3 The **Soaker Catheter** may be used in I-Flow's Pain Management Systems such as K982946 and K984502.

3.0 BIOLOGICAL SPECIFICATIONS

3.1 All materials in the catheter are identical in formulation to materials currently being used in other products with the same or similar uses and have a long history of use in those devices.

3.2 Biological testing is in conformance with ISO 10993 Part 1 for fluid path components.

4.0 CHEMICAL AND DRUG SPECIFICATIONS

4.1 Drug Compatibility and Stability

4.1.1 There are no specific drugs referenced in the labeling for the **Soaker Catheter**.

4.1.2 There are no drugs included in the **Soaker Catheter**.

5.0 INTENDED USE

5.1 The **Soaker Catheter** is intended to be used as follows:

5.1.1 With I-Flow Corporation's PainBuster, ON-Q and Nerve Block pain management kits; and

5.1.2 As a stand alone device to provide continuous or intermittent delivery of local anesthetics or narcotics to surgical wound sites and/or close proximity to nerves outside of the epidural space. Routes of administration may be intraoperative, intramuscular, subcutaneous or percutaneous.

5.2 The catheter is single patient use only.

93

6.0 LABELS AND LABELING

6.1 I-Flow Corporation believes the proposed labels and labeling, where appropriate, meets the requirements of 21 CFR Part 801 as it relates to a determination of intended use and adequate directions for use.

7.0 STANDARDS

7.1 There are currently no standards established for anesthetic catheters.

8.0 PACKAGING

8.1 The catheter is packaged in either a Tyvek pouch or a form/fill/seal tray.

9.0 COMPARISON TO LEGALLY MARKETED DEVICES

9.1 The **Soaker Catheter** is substantially equivalent to the (1) I-Flow IntraOp Catheter submitted in K991543, (2) Teleflex Medical (TFX) Epidural Catheter (K840202, originally submitted by Aries) (3) the B. Braun Perifix Set (K813186) and (4) the Epimed International FETH-R_KATH catheter.

9.2 Device Descriptions

9.2.1 Comparisons

9.2.1.1 This submission is intended to notify the Federal Food and Drug Administration that I-Flow Corporation intends to add an additional model to the family of **Soaker Catheters** formerly referred to as the IntraOp Catheter (K991543). The new model is virtually identical to the predicate 2.5 inch Soaker Catheter except that the new model will have a 5.0 inch infusion segment.

9.2.1.2 All the catheters provide a catheter connector device similar to a Touhy Borst connector or a molded luer lock connector.

9.2.2 Based upon the data presented in this section, I-Flow Corporation has determined that the **Soaker Catheter** is substantially equivalent to the named predicate devices.

94